

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION**

**Coordinating Office for Terrorism
Preparedness and Emergency Response (COTPER)
Board of Scientific Counselors (BSC)**

**Meeting Minutes
August 13-14, 2009**

| Table of Contents | Page |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| Acronyms | 3 |
| Call to Order / Welcoming Remarks / Introductions / FACA Review / COIs | 5 |
| Competency Model Project Overview | 6 |
| Program Response to BSC Recommendations from Fiscal Allocation Process (FAP) External Peer Review | 13 |
| Welcome from the CDC Director | 20 |
| BSC Peer Review Status Reports | 23 |
| COTPER Program Updates | 38 |
| Public Comment – Day 1 | 51 |
| Call to Order / Welcoming Remarks – Day 2 | 52 |
| Division of Select Agents and Toxins External Peer Review by Homeland Security Institute (HSI) / Technical Comments from Program / Discussion / Vote | 53 |
| BSC Peer Review Topics for FY2010 / Meeting Structure | 71 |
| Updates from Liaison Representatives | 73 |
| Ask-the-Board Session | 77 |
| Public Comment – Day 2 | 78 |
| Closing Remarks / Adjourn | 78 |
| Certification | 78 |
| Appendix A: Membership Roster | 79 |
| Appendix B: List of Attendees | 82 |

Acronyms

| | |
|--------|-----------------------------------------------------------------------------|
| APHIS | Animal and Plant Health Inspection Service (USDA) |
| APHL | Association of Public Health Laboratories |
| ASPH | Association of Schools of Public Health |
| ASPR | Assistant Secretary for Preparedness and Response (HHS) |
| ATSDR | Agency for Toxic Substances and Disease Registry (CDC) |
| BARDA | Biomedical Advanced Research and Development Authority |
| BSC | Board of Scientific Counselors |
| BCU | Biosurveillance Coordination Unit (CDC) |
| CA | Cooperative Agreement |
| CCID | Coordinating Center for Infectious Diseases (CDC) |
| CDC | Centers for Disease Control and Prevention |
| CEFO | Career Epidemiology Field Officer (CDC) |
| COTPER | Coordinating Office for Terrorism Preparedness and Emergency Response (CDC) |
| CPHP | Centers for Public Health Preparedness |
| CRI | Cities Readiness Initiative |
| CSTE | Council of State and Territorial Epidemiologist |
| DEO | Division of Emergency Operations (CDC) |
| DEOC | Director's Emergency Operation Center (CDC) |
| DFO | Designated Federal Official |
| DHS | U.S. Department of Homeland Security |
| DHHS | U.S. Department of Health and Human Services |
| DIA | Defense Intelligence Agency |
| DoD | Department of Defense |
| DOJ | Department of Justice |
| DSAT | Division of Select Agents and Toxins (CDC) |
| DSLRL | Division of State and Local Readiness (CDC) |
| DSNS | Division of Strategic National Stockpile (CDC) |
| ECO | Enterprise Communication Office (CDC) |
| EOC | Emergency Operations Center (CDC) |
| EPA | Environmental Protection Agency |
| ERPO | Extramural Research Program Office |
| FACA | Federal Advisory Committee Act |
| FDA | Food and Drug Administration |
| FO | Fiscal Office |
| FMO | Financial Management Office |
| FY | Fiscal Year |
| GAO | Government Accountability Office |
| GIS | Geographic Information System |
| GSA | General Services Administration |
| HAN | Health Alert Network |

| | |
|---------|------------------------------------------------------------|
| HHS | Health and Human Services |
| HSI | Homeland Security Institute |
| HSsal | Homeland Security Studies and Analysis Institute |
| HSPD-21 | Homeland Security Presidential Directive 21 |
| ICS | Incident Command System |
| IND | Improvised Nuclear Device |
| IOM | Institute of Medicine |
| LRN | Laboratory Response Network (CDC) |
| MRSA | methicillin-resistant <i>Staphylococcus aureus</i> |
| NACCHO | National Association of County and City Health Departments |
| NBAC | National Biosurveillance Advisory Subcommittee |
| NBSHH | National Biosurveillance Strategy for Human Health |
| NGOs | Non-Governmental Organizations |
| NIH | National Institutes of Health |
| NIHB | National Indian Health Board |
| NSAR | National Select Agent Registry |
| OD | Office of the Director |
| OEMB | Outcome Evaluation and Monitoring Branch |
| OMB | Office of Management and Budget |
| OSPHP | Office of Science and Public Health Practice |
| OSI | Office of Strategy and Innovation |
| OWCD | Office of Workforce and Career Development (CDC) |
| PAHPA | Pandemic and All Hazards Preparedness Act |
| PERRC | Preparedness and Emergency Response Research Centers |
| PHEP | Public Health Emergency Preparedness Cooperative |
| PHER | Public Health Emergency Response |
| PSB | Program Services Branch |
| RDD | Radiological Dispersal Devices |
| RFP | Request for Proposal |
| RWJ | Robert Wood Johnson |
| SAP | Select Agent Program |
| SIO | Strategy and Innovation Office (CDC) |
| SME | Subject Matter Expert |
| SNS | Strategic National Stockpile (CDC) |
| TLC | Target Capabilities List |
| TPER | Terrorism Preparedness and Emergency Response TPER |
| USDA | United States Department of Agriculture |
| WMDs | Weapons of Mass Destruction |

THURSDAY, AUGUST 13, 2009**Call to Order / Welcoming Remarks / Introductions / FACA Review / COIs**

Barbara Ellis, Ph.D., Deputy Associate Director for Science, COTPER; DFO COTPER BSC
Ellen MacKenzie, Ph.D., Member, COTPER BSC
Richard E. Besser, M.D., Director, COTPER
Dan Sosin, M.D., M.P.H., Senior Advisor for Science, COTPER

Dr. Barbara Ellis, Designated Federal Official, welcomed everyone, officially convening the Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER) Board of Scientific Counselors (BSC) meeting. In addition to reviewing housekeeping issues, she reminded everyone that the BSC functions include administering external peer review of COTPER research and science, including non-research programs; providing advice to the Secretary of Department of Health and Human Services (HHS), the Director CDC, and the Director COTPER concerning strategies and goals for programs for research within COTPER; performing secondary peer review of applications for grants and aid for research and research training activities, cooperative agreements, and research contract proposals related to broad areas within COTPER; and monitoring the overall strategic direction and focus of scientific programs in COTPER offices and divisions.

Dr. Ellis expressed her personal gratitude to Drs. Besser and Sosin for their leadership and support for all of the BSC activities, and acknowledged and thanked Matthew Jennings, Diane Manheim, Miguel Cervantes, Kim Gadsden-Knowles, and Marinda Logan for their roles in helping to plan the meeting. Diane has accepted another position at CDC and has promised to generously make time to provide support as she has in the past. In the absence of a permanent chair, Dr. Ellis thanked Dr. Ellen MacKenzie for her willingness to lead this BSC meeting.

Dr. MacKenzie extended her welcome to everyone, especially thanking them for taking time out of their busy schedules to participate in this BSC meeting. She reviewed the meeting procedures, led those present in a round of introductions, and reviewed the meeting agenda. She then introduced Dr. Besser, lamenting that he would soon leave CDC as he had accepted a position as Senior Health and Medical Director at ABC News.

Dr. Besser offered his welcome to the members, acknowledging the major commitment they were making to be a part of the BSC, and expressing CDC's gratitude for their service. In order for COTPER to improve its programs and advance the science pertaining to preparedness and response, they really needed the BSC's input, and the input of others. In reflecting upon the accomplishments that he was proudest of during his tenure with COTPER, establishing and receiving input from the BSC was an achievement he expected to have lasting impact on the program. Dr. Besser said that he was pleased to announce that Dr. Dan Sosin had agreed to serve as the Acting Director of COTPER, which would provide great continuity, as well as a renowned scientist who truly understood the work of COTPER and appreciated the value that science had in moving COTPER's programs forward. He concluded that the selection of Dr. Sosin would be a plus for science in the area of emergency preparedness and response, thanking Dr. Sosin for agreeing to take on this role.

Dr. Sosin added his welcome, noting that it was somewhat like a family reunion. He reported that since last they met, a number of changes had occurred: Drs. Koh and Hamburg left upon accepting senior roles with the Department of Health and Human Services (HHS); and Jim Terbush was replaced by Amy Kircher as an *ex officio* member of the BSC. Dr. Sosin stressed the importance of the *ex officio* members and liaisons, pointing out their vital importance to the work of the BSC. He stressed that although Dr. Besser would be departing COTPER, the BSC members were brought on to “look under the hood,” deeply reviewing the programs and offering critical advice. The premise under which they were brought on would not change. There are many formalities of a Federal Advisory Committee Act (FACA) level Board of Scientific Counselors in providing advice to the federal government. Dr. Sosin assured the members that COTPER would abide by those regulations, and would expect the BSC to follow them as well. He emphasized that at the same time, the overarching goal pertained to strengthening the national preparedness and emergency response by helping, steering, and guiding CDC in the way that best served the role that COTPER plays in a broad network of emergency preparedness and response throughout the country. He thanked the members from the bottom of his heart for their efforts toward that goal. He requested that the members be open, critical, and collaborative in developing the advice and accommodating the wide range of perspectives—no holds barred.

Dr. MacKenzie announced that at the conclusion of this BSC meeting, all board members and liaisons were invited to a reception for Dr. Besser. On the behalf of the BSC, she thanked Dr. Besser for all of his contributions during his time with CDC.

Dr. Ellis added that Bonnie Hillsberg, the BSC’s National Indian Health Board (NIHB) liaison, had resigned from NIHB, leaving that liaison position vacant. With respect to FACA rules, she then reviewed conflict of interest issues. She requested that each board member review the conflict of interest (COI) forms that were completed prior to the meeting to ensure their accuracy and make any changes or additions as necessary. No members declared any additional conflicts. BSC members were asked to sign the completed forms and hand them to Matthew Jennings or Miguel Cervantes. In conclusion, Dr. Ellis reviewed additional materials in their CDC folders (e.g., updated agenda, table of contents, COTPER peer review standard operating procedures, a scope for a program review proposed for FY2010, and an evaluation form. She emphasized the importance of the evaluation form, requesting that members complete and submit these forms at the close of the meeting prior to departing.

Competency Model Project Overview

Andrea Young, Ph.D.
Senior Learning Officer for Preparedness and Response
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

Dr. Young expressed her excitement about the Preparedness and Response Core Competency Model Development Project, extending her gratitude and recognition of the Association of Schools of Public Health (ASPH), which has been COTPER’s very strong partner in this endeavor.

This project was a direct result of the Pandemic and All-Hazards Preparedness Act (PAHPA), which mandates the establishment of competency-based training and curricula. Dr. Young specifically highlighted the following text from PAHPA, Section 304(d), which states,

The Secretary, in collaboration with the Centers for Public Health Preparedness and other public or private entities shall . . .

- Establish core curricula based on established competencies leading to a 4-year bachelor's degree, a graduate degree, a combined bachelor and master's degree, or a certificate program*
- Facilitate the development of a competency-based training program to train public health practitioners*

As evidenced by those two bullets, competencies drive and inform curricula that are to be implemented in academic settings, the public health workforce, and the practitioner community. COTPER clearly realized a requisite activity to develop and roll out curricula for these groups to include an up to date, valid set of competencies for public health preparedness and response. Thus, their project objective is “to develop a model of core competencies for public health preparedness and response.”

With respect to the approach, Dr. Young explained that competencies are areas of knowledge, skills, or characteristics that are observable and result in effective or superior performance on the job. Simply put, a competency defines optimal performance in a role or a job. Competency models can be used in a variety of ways, and they are a key human resource tool for selecting talent, training and development (the primary reason for this particular project), performance appraisals, and succession planning. It is COTPER's hope that the resulting competency model can be used across those avenues, and will directly help COTPER with the Centers for Public Health Preparedness (CPHP) program and informing the curriculum that they develop.

In terms of the project's guiding principles, COTPER worked with a leadership group to gain clarity about what the resulting competency model would do and what the boundaries would be. The determination was that the resulting competency model would: provide a proposed national standard of skills; be behaviorally-based, with a focus on observable actions; reflect and build upon existing competency models; align with the Department of Homeland Security (DHS) Target Capabilities List; target members of the public health workforce; apply to all hazards scenarios; supplement existing public health competency models; be utilized by the Centers for Public Health Preparedness grantees in 2010; and be available to other public and private entities—it will not be exclusively used by the CPHP, and it is not a model specifically for CDC.

The project approach and methodology is a complicated process, with four overarching phases. First, and most importantly, is partnering with the ASPH through their current cooperative agreement with CDC. This step is in place, and COTPER has been working with ASPH over the past few months. To avoid duplication of efforts, COTPER is building upon competency models that already exist, and is in the process of conducting a comparison analysis of existing and relevant competency models. The third step is to engage subject matter experts (SMEs) from academia and the practice community through three overarching mechanisms: a Leadership Group, a series of focus groups of subject matter experts, and three Delphi rounds. The fourth step is to solicit BSC feedback on the competency model, after presenting the membership with background and an update on the project. The hope is to request BSC review of the project in April 2010.

The four competency models to be compared include the following:

- ❑ Core Competencies for Public Health Professionals, developed by the Council on Linkages, which was recently updated in 2009;
- ❑ A Consensus-Based Educational Framework and Competency Set for the Discipline of Disaster Medicine and Public Health Preparedness (*Disaster Medicine and Public Health Preparedness Journal*, American Medical Association, 2008);
- ❑ Master's of Public Health Degree Core Competency Model developed by the ASPH and others in 2007; and
- ❑ Bioterrorism & Emergency Readiness: Competencies for All Public Health Workers, developed by Columbia University in 2002.

When COTPER convened the Leadership Group, the focus was largely on determining what components of these models would be most informative for COTPER's work. The consensus in the leadership group was that the AMA model, which combines medical and public health preparedness, has competency domains that are highly relevant to both disciplines. That would be a key driver in the work COTPER does in the comparison analysis. The second most relevant model is Columbia University's Bioterrorism & Emergency Readiness: Competencies for All Public Health Workers model, which also helped COTPER to be clear that the public health preparedness and response competency model would be supplemental to existing core public health competencies.

At the time of this COTPER BSC meeting, the Leadership Group had met once. It is comprised of 17 experts in preparedness and response who represent public health practice and schools of public health. The split is fairly equal between state, local, federal, and non-governmental organizations (NGOs). Their charge is to establish the competency model framework; guide the development of core competencies and behavioral anchors; promote the project with critical stakeholders; and consider ideas and concerns of their own constituent groups and key partners about the project. The membership is as follows:

Leadership Group Co-Chairs:

- Audrey Gotsch, University of Medicine and Dentistry of New Jersey School of Public Health
- C. William Keck, Northeastern Ohio Universities College of Medicine

Leadership Group Members:

- Richard D. Clover, University of Louisville, School of Public Health and Information Sciences
- Kimberly Elenberg, Office of Force Readiness and Deployment, Office of the Surgeon General, Department of Health and Human Services
- Kristine M. Gebbie, Hunter-Bellevue School of Nursing, City University of New York
- James J. James, Center for Public Health Preparedness and Disaster Response, AMA
- Michael T. Handrigan, Emergency Care Coordination Center, Office of the Assistant Secretary for Preparedness and Response
- Kraig E. Humbaugh, Division of Epidemiology and Health Planning, Kentucky Department of Public Health

- David Marcozzi, Office of Preparedness & Response Operations, Department of Health and Human Services
- D. W. Chen, Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense
- Kathleen Miner, Emory University Rollins School of Public Health
- Vanessa Murphy, Rensselaer County Department of Health, New York
- William J. Riley, University of Michigan School of Public Health
- Steven J. Rottman, Center for Public Health and Disasters, University of California at Los Angeles School of Public Health
- D. Kenneth W. Schor, Uniformed Services University of the Health Sciences
- Peggy Wittie, Health Care Services, Collin County Health Department, Texas
- Andrea Young, COTPER, CDC
- Craig Thomas, COTPER, CDC (*Liaison*)

With respect to the series of focus groups and Delphi rounds, participants for both are being solicited and recruited through the ASPH's website. As of August 7, 2009 over 214 volunteers representing the practice community (57%) and academia (43%) had been recruited. The focus groups will be utilized to define the competencies and the behavioral anchors. Delphi rounds will be used to distill competency statements and establish consensus on the relative importance of proposed competencies. The project plans and timeline are as follows:

| Date | Action |
|------------------------|-------------------------------------------------------------------------------------------|
| July-August 2009 | Develop draft competencies |
| August 13, 2009 | Present Project Background to BSC |
| August 26-27, 2009 | Convene Focus Group 1 in Atlanta |
| August 31, 2009 | Convene Leadership Group meeting |
| September 2009 | Conduct Delphi round 1 Revise draft competencies Develop initial behavioral content |
| September-October 2009 | Identify behaviors for competencies |
| November-December 2009 | Conduct Delphi round 2 Modify model content |
| November 7-10, 2009 | Share updates at ASPH/APHA Annual Meetings in Philadelphia |
| December-January 2010 | Conduct Delphi round 3 Finalize model content |
| February 2010 | Share updates at Preparedness Summit |
| March 2010 | Convene Leadership Group to integrate model content |
| April 2010 | Submit model to CDC COTPER Board of Scientific Counselors (BSC) for external review |
| May 2010 | Consider BSC comments to draft updated model for review by Leadership Group |

| | |
|------------------|-----------------------------------------------------------------------|
| June 2010 | Circulate model to broad external audience and monitor input/comments |
| July – Sept 2010 | Disseminate competencies to public |

COTPER is working at a very fast pace. Usually competency models take approximately two to three years to develop; however, this one will be developed essentially a year. Dr. Young indicated that she was looking to the BSC for external validation of the competency model. The feedback from that review will be used to further refine the model, which is to be completed in time for dissemination to coincide with the awards for the new Centers for Public Health and Preparedness. For further information about the project, she directed participants to the website at: www.asph.org/document.cfm?page=1081, which is to be updated regularly. She also invited anyone interested to participate in the focus groups and / or Delphi rounds.

Discussion Points

A BSC member thought this sounded like an exciting program on which good progress was being made, pointing out that there would soon be a new round of the 5-year cycle for Public Health and Emergency Preparedness (PHEP) grants. This member wondered whether COTPER had any integration plans with the PHEP program, as well as what the plans were to test the models.

Dr. Young responded that with regard to PHEP integration, PAHPA further defines the work of the CPHP into three specific categories. One is academic competency-based curricula to be delivered in schools of public health. There is also the core competency-based training program, which is directed toward the public health workforce. The intention is to directly support state and locals in terms of prioritizing, identifying, and delivering quality training that is aligned with knowledge and skills that are defined as being critical foundation skills for any type of preparedness and response within the public health workforce. She viewed this as the resulting core competency training program which would come out of the competencies and is expected to directly benefit state and locals, and also provide some consistency across the nation with regard to training priorities and making them accessible. The last part of PAHPA addresses this, although it is somewhat misnamed in that it is referred to as "Academic Workforce Communication." Current work of the CPHP is to identify a need at the state level and develop a training program to meet that particular need. COTPER realizes that a core curriculum is not the end all, and that there are training and development needs that fall outside of what is considered core foundation. Through PAHPA, it is clear that centers will have that built into the new program and will have an opportunity to provide unique training solutions and structural interventions that fall outside of the core. COTPER's intent is to standardize training, which will directly align with the PHEP. The new program will not be used to meet unique needs that fall outside of that. With regard to testing the validity and reliability of the competencies in the model, the competencies are essential to being able to do that. One of the struggles has been that there is no baseline or universal competency set, at least in terms of the CPHP. Many groups use the Columbia model, but the program has not been structured to systematically, and at a more aggregate level, measure that. As specifically called out in PAHPA, evaluation will be a key component of the new model. The evaluation will not only assess immediately gained knowledge following completion of the training, but also if / how the knowledge and skills gained are being applied.

A BSC member wondered how this fit into the broader context of emergency management preparedness competencies [e.g., Incident Command System (ICS) Training], inquiring as to how successful they were at tracing the target capabilities list to the individual to make that tie, and whether any consideration was given to involving non-public health emergency managers in the Delphi process.

Dr. Young responded that in the initial leadership group meeting, it was on the top tier list. There was no argument that the public health workforce needs to be trained on ICS in order to be able to integrate into a response in a coordinated fashion. This really applies to all disciplines, not just public health. While the competencies are not yet developed, they are expected to align with ICS kinds of competencies. In terms of the target capabilities, COTPER is committed to being able to have a line of sight, or a mapping, with the target capabilities so that those measures line up. How exactly that will occur and which particular competency buckets will be aligned to which particular capabilities out of that very long list has yet to be determined. In terms of the overarching framework, it is important to COTPER to at least have a line of sight.

Given that there are already a number of competency models, a BSC member requested more information about the gaps in those models and how COTPER planned to avoid duplicating work that was already done.

Dr. Young responded that a crosswalk analysis was done that lists all of the competency domains and competencies of the various models. In most cases, there are slight variations of language versus clear gaps. The Columbia competencies are very comprehensive and have been very useful. Part of the problem with that is they were developed in 2002, so it is important to recognize where the field has gone in the past seven years and to ensure that the competency model takes this into consideration. The AMA and the Columbia competency models align pretty nicely in terms of their broad buckets. It is more a process of defining and refining what is now known about knowledge and skills in those particular areas, making it current, and validating the particular competency model. She stressed that the purpose of the COTPER competency model was to serve as a core curriculum versus having a competency model anybody wants to use be the basis for curricula, at least for the grantees and the CPHP program.

An *ex officio* member indicated that the Health Affairs Office at Homeland Security has public health personnel who are intimately involved and actually co-leading the TCL 3.0 effort. These are the same people who are also involved with helping to develop competencies in the emergency management realm. It was suggested that COTPER make an effort to reach out to this group for assistance.

Dr. Young expressed gratitude for the suggestion. She also mentioned that the Federal Education Training Interagency Workgroup, which is directly in response to Homeland Security Presidential Directive 21 and PAHPA with regard to coordinating across agencies and departments, is very interested in the establishment of competencies. She sits on that group, has read DHS's briefing, and has partnerships with DHS in terms of the work they are doing in this area. In addition, she is aware of the ICS competencies coming out of FEMA, and the importance of ensuring that COTPER is clear in terms of how those fit into the structure of its competencies.

A BSC member pointed out that there is always a disconnect in the competency discussion in that everyone talks a lot about the development of the competencies, but does not spend any

time on the demonstrations of action. It seemed that if the competencies were only tied to the academic training, they would miss the way these get put into practice. There needs to be some discussion about what will demonstrate that the competencies have been met, other than passing or going through an academic course or practice training. They must move beyond the concept of competency as a learning objective to an actual demonstration of implementation and practice.

Dr. Young agreed, indicating that the competencies which go beyond just training and education should be describing behaviors that people should be able to demonstrate on the job. From there, learning objectives should be developed that drive the training and education. That is what should be measured at the very end of a particular course or training. It feeds very nicely off of the evaluation question in terms of being able to know whether people are able to do what they were taught to do, and that time is being taken to measure whether they are able to do that. It does speak to the fact that competency model is more than just a frame of training and education. It relates directly to how position descriptions are written, how people are selected for particular jobs and roles, and how their performance is assessed. It is part of a broader system. While they had been focusing very much on the curriculum component, she recognized that competencies are broader than that.

A BSC member noted that a lot of work has been done by the Gallup Organization with respect to talents. They developed an instrument called Strength Finder 2.0, and they argue that the way people are selected for training may be dependent upon the strengths that they have. Thus, the characteristics of the people going through training must be assessed in terms of whether they can deal with that training in an appropriate manner relative to the strengths that they have. There is linkage that is often left out of the competency discussions, which is the research question.

A liaison pointed out that one of the problems with the balance of some of the metrics and putting those into place to measure how effective someone is in their role is regional issue. This may be a particular issue with local health departments in particular, given that some are in resource-rich areas and others are in areas without ample access to resources. There are also local variations in terms of practice abilities and legalities pertaining to what they can and cannot do. Those discrepancies must also be addressed. If someone is trained to fit into a system that has been in existence for many years, there is automatically a disconnect, often because they are discouraged by having to overcome that existing system.

Dr. Young responded that the competency model she was talking about was really a broad and foundational core competency model. In terms of the nuances mentioned by the liaison member, she suggested that training may not be the solution as they fall outside of a core competency-based training program. She thought that was why those who wrote PAHPA intended to address unique, context-specific training needs. The broad and foundational competency models did not eliminate the need for context-specific training for particular localities.

A liaison member complimented Dr. Young in pulling this process together as quickly as she had. It has been a pleasure for schools of public health and ASPH to work with her. Although faculty members at schools of public health have a lot of experience in developing competencies, they also understand the existence of duplication. Every faculty member at every school must develop their own competencies to some extent. Having a common baseline is extremely important. Not only can these initially be applied to particular courses, certificates,

or degrees to which people will be applying, but also it can be coordinated with competency measurement in the workforce as well.

A member of a school of public health agreed that this would be enormously beneficial.

Program Response to BSC FAP External Peer Review Recommendations

Kim Lindsey, Ph.D.

**Fiscal Officer, Office of the Chief Management Officer
COTPER, Office of the Director**

Dr. Lindsey said that she was thrilled to present the program response to the BSC's recommendations for the review of COTPER's Fiscal Allocation Process (FAP). She explained that the FAP is COTPER's process to allocate Terrorism Preparedness and Emergency Response (TPER) funding across the agency. The FAP is composed of 5 main stages and also stage 6, which informs the next year's process but is not part of the FAP. Stage 1 is preplanning and priority setting, and is managed by the Strategy and Innovation Office (SIO) within COTPER. Stage 2 is the call for proposals and guidance. Once the priorities are set by the agency-wide priority team, the guidance for the FAP for new proposals that will come in from across the agency for funding are based on those priorities. Proposals that are mirrored or married to the guidance are announced in about May of each year. In May 2009, the call for new proposals for funding with the terrorism preparedness and emergency response appropriations went out for FY2010. Stage 3 consists of a primary objective review of all of the proposals submitted within an enterprise wide system called the HealthImpact.net (HI.net) system at CDC. HI.net closes on June 30th, so the primary objective review is conducted during early July. This review is comprised of SMEs from across the agency who are in multiple areas (e.g., epidemiology, laboratory, public health system support), and they rank and vote on the merit of the new proposals that are received for funding for the next fiscal year.

Stage 4 involves a secondary review and the selection process. Once the merit ranking of the new proposals received is completed, a secondary review is conducted to ensure that the proposals received align with the preparedness priorities defined in Stage 1. Any proposals that do not align are eliminated from the funding list. In Stage 4, another score is assigned for relevance to preparedness priorities and the coordinating center director's priorities. Following Stage 4, an assessment is made regarding how much funding is anticipated for the next fiscal year, and identification is made of which new proposals will be funded for terrorism preparedness and response activities for the next fiscal year. Stage 5 involves communication of the results to the coordinating centers and offices. Once the funding is received on October 1 (e.g., the beginning of the next fiscal year) Stage 6 is initiated, which is the performance measurement and evaluation component. Once an awardee receives their funding, their agreed upon milestones are checked twice a year.

An ad hoc workgroup of the COTPER BSC was convened on February 25-27, 2009 to review the current state of COTPER's FAP; assess the transparency, reliability, and accountability of the FAP; and develop and share recommendations to improve the FAP. Professor Sharona Hoffman chaired this group, which was incredibly engaged. Out of this meeting came 14 recommendations that fell into 4 main categories: strategic planning; management; submission and review of proposals; and evaluation, lessons learned, and feedback. Three of the 14 recommendations provided by the BSC followed similar implementations and were consolidated

in to one response. In order to respond to the recommendations, the following definitions were set forth:

- ☐ *Concur*: We agree and we have the funding, staff, and control over the means to begin implementation of the recommendation.
- ☐ *Concur in principle*: We agree, but we do not have the funding and / or the staff and / or control over the means to begin implementing the recommendation. Necessary funding has been requested or other modification to implement the recommendation, and we will implement if the requested funding / modification is approved.
- ☐ *Non-concur*: We do not agree with the recommendations presented and have provided feedback.

For the record, Dr. Lindsey indicated that COTPER did concur or concur in principle with every recommendation that was made by the BSC. She identified for each recommendation whether responsibility fell to the Fiscal Office (FO), the SIO, or both.

Under strategic planning, there were two recommendations. The first recommendation is to use input from leaders who have access to and knowledge of threat assessments to inform COTPER's process. To this, COTPER concurs in principle, given that in order to have access to the threat assessments that come from the intelligence agencies they have to have a Top Secret Clearance. She and Peter Rzeszotarski currently hold a Secret level clearance (Fiscal Officer and Strategy and Innovation Officer, respectively) but have requested funds to receive a Top Secret clearance, which is a very long process. Nevertheless, it is included in the budget. If it is funded, the necessary steps will be taken to acquire this clearance level. In addition, they will work with SMEs from across the agency, most of whom already have this clearance level, to ensure that on the front end they are incorporating what the intelligence agencies are stating should be scenarios that COTPER should be prepared for.

The second strategic planning recommendation is to use foresight techniques to inform the FAP that include broad environmental scans of social, economic, and technological factors that could impact threat; and envision new scenarios. COTPER concurs in principle with this recommendation. Regarding the specific means to address or implement the recommendation, COTPER's Enterprise Communications Office (ECO) could be tasked with performing these broad environmental scanning functions. However, this office is currently not staffed appropriately to conduct this broad level environmental scanning function. In terms of milestones, the SIO and ECO will request funding to conduct futures research. SIO and ECO will engage partners, including the Extramural Research Program Office (ERPO) to identify emerging issues. SIO will request inclusion in agency-wide scenario-development activities.

The second category is management, under which the third through sixth recommendations fall. The third recommendation is under the SIO's purview and is to seek more input and collaboration with outsiders in order to generate more original ideas. COTPER concurs in principle with this recommendation. In terms of the specific means to address or implement this recommendation, FACA limits the extent of involvement with non-federal outsiders. COTPER's mechanisms for collaboration include five objective advisory groups, three policy priority workgroups, revision of public health components of the Target Capabilities List (TCL), and cross-walking policy and planning documents with external partners. Regarding milestones, SIO will engage the objective advisory and policy priority groups, and will continue the TCL revisions and the cross-walk of policy documents.

The fourth recommendation, also within the SIO lane, is to link costs, budgets, and performance data so that leadership has information about the costs, benefits, risks, and redundancies of the investment choices. COTPER concurs in principle with this recommendation. Regarding the specific means to address or implement this recommendation, COTPER submits an annual performance budget document with content dictated by OMB, HHS, and CDC's Financial Management Office (FMO). Risk and redundancies are generally not included in this document. COTPER's Strategic National Stockpile (SNS) program has implemented a system to track budget performance but it does not fit the needs for this recommendation. COTPER uses HealthImpact.net (HI.net) to help track activity investment. The system is managed by CDC's Office of the Director (OD) and is not configured to provide the data called for in this recommendation. Regarding milestones, SIO will provide the FO with annual performance budget data. FO will submit system recommendations to change HI.net to fulfill recommended data requirements. Evaluation studies will continue to occur with a focus on cost-benefit analysis. A change will be requested in the template used to submit the annual performance budget data to include risks and redundancies. COTPER formed a program partners workgroup to address and eliminate redundancies identified by stakeholders. Within the review, during the stakeholder portion, a number of SMEs across the agency spoke to their frustration that different parts of the agency do not necessarily understand what other parts of the agency are doing in terms of preparedness and response activities. While it is not a recommendation on its own, COTPER decided to form the program partner's work group to include SMEs from across CDC. They are funded to conduct terrorism, preparedness, and response activities. They will meet every quarter to present a program review and discuss barriers or hot topics so that everyone hears the same information.

The fifth recommendation, which falls under the purview of SIO and FO, is to the extent that there is flexibility, take advantage of it. Encourage partnerships with other parts of CDC to support innovative projects. COTPER agreed in principle with this recommendation. Regarding the specific means to address or implement this recommendation, funding language for Congressionally-required activities is narrow. In the past, SIO has submitted budget-restructuring language three times to provide recommended flexibility. With respect to partnerships, FO leads an agency-wide terrorism preparedness and emergency response program partners group. A workgroup was formed as a result of the BSC. Of the new proposals this year, 21% reflected partnerships with two or more units within the CDC. That really speaks to the importance of reviewing the process. The greatest struggle is that 91% of COTPER's appropriation is congressionally mandated, so there is no flexibility and few funds available for new and innovative work at CDC. However, they continue to receive congressionally required projects, most of which do not come with funds.

The sixth recommendation within the management category is to strengthen capacity to measure operations and projects using internal and external experts; engage external subject matter experts to serve as peer reviewers; and create mechanisms for an independent peer review process for ongoing programs. This is the recommendation under which three of the 14 recommendations were subsumed into one for the purposes of the program response. COTPER agrees in principle with this recommendation. Pertaining to the specific means to address or implement the recommendation, SIO budgets do not include travel, lodging, or per diem for external experts. Funds will be needed to support the travel of five external experts to participate in discussions. Regarding milestones, a request has been made for \$20,000 in FY2010 to support travel for five external experts. If approved, external experts will be identified. Teleconferences will be convened with external experts for quarterly program

reviews. External experts will participate in discussions with agency SMEs and participate in the Primary Review Panel of the FAP.

The next category, submission and review of proposals, includes the seventh through tenth recommendations. The seventh recommendation is that while some ongoing activities must be funded, all others should be reviewed more critically. COTPER concurs with this recommendation. With regard to the specific means to address or implement, separate ongoing activities fall into two categories: 1) ongoing congressionally-required activities that must be funded; and 2) all other non-required ongoing activities. The milestones are to define the TPER activities that must be funded, and separate these from all other activities; review all other activities more critically than "must be funded;" and explore the possibility of requiring SME reviewers to review the "must be funded" activities every four years as opposed to every other year.

The eighth recommendation, under the purview of FO, is to initially call for three-page concept papers, then select the top 10 choices, requiring only those to submit a full proposal and peer review with external experts. COTPER agrees with this recommendation in principle. Dr. Lindsey stressed that she loved this idea so much that she talked about it across the agency. Feedback received agency-wide indicated that activity leads preferred to write only one proposal. Pushback may have been attributed to the novel H1N1 Influenza outbreak and competing priorities.

The ninth recommendation is to tailor HI.net to fit all of COTPER's needs. Originally, Dr. Lindsey did not concur with this. However, once she listed the definitions for concurrence, she realized that COTPER concurs in principle. Regarding the specific means to address or implement this recommendation, HI.net is a CDC enterprise system and is not owned by COTPER. All other coordinating center/office needs and priorities compete with COTPER's needs. COTPER is permitted to submit change requests to update HI.net. These needs are considered within the HI.net budget and agency priorities and needs. Every year, COTPER has the opportunity to submit changes that they would like to have for the HI.net system to better meet its needs; however, all other coordinating centers and offices at CDC are doing the same. Still, COTPER will continue to identify its needs through this process and submit to OSI.

The tenth recommendation falls within the SIO lane, and is to institutionalize the link between one year's FAP and the next year's planning and budget formulation process. COTPER agrees with this recommendation in principle. Regarding specific means to address or implement this recommendation, the federal fiscal process formulates budgets two fiscal years from current execution year and FAP addresses budget allocation one fiscal year from current execution year. COTPER is trying to formalize the linkage between those two processes rather than focus on specific fiscal year. Once capabilities are costed out, a link can be established between one year's FAP and the outlying year's budget formulation. In terms of milestones, COTPER intends to create a capabilities-based matrix that overlays cost to achieve or sustain each capability, and to request permission to include the matrix in the next budget formulation submission.

The next category is evaluation, lessons learned, and feedback. This includes the eleventh and twelfth recommendations. The eleventh recommendation, which falls in the FO lane, is to discontinue funding for under-performing projects and shift that funding to more prioritized activities. COTPER wholeheartedly concurs and currently does this. At this time, every activity that COTPER funds is performing at the minimal acceptable level of performance at a B on the grade scale. They must be performing at 80% or higher, or they will lose their funds. There are

two reporting periods. If the first reporting period is at less than the acceptable level, Dr. Lindsey meets with the division director and management officer to inform them that they will lose their funding at the next reporting period if they do not meet the minimum requirement. There is currently a caveat because CDC is busy preparing for a response to H1N1, so some of the scientists and program personnel may be sent to work almost exclusively in H1N1. Therefore, Dr. Lindsey assumes that there will be some performance issues because staff will be taken off of their regular duties to respond to some degree to the pandemic.

The twelfth recommendation is to shift to a two-year FAP and adjust the process every two years, or keep the annual FAP and adjust the guidelines and processes for proposal submissions and review every two years. COTPER concurs with this recommendation. Dr. Lindsey has already started brainstorming this recommendation, which the whole office and leadership in COTPER bought into. She has already started implementing this and, this year, she did not review the ongoing activities as they will do that next year. This year, they only focused on new proposals rather than spending considerable time assembling 400 reviewers to review activities that they are required to do. Of the TPER appropriation, 91% is Congressionally-required and the amount of discretionary funding is decreasing. The FO shifted to a two-year FAP for FY2010 ongoing activities and limited the number of new proposals. Agency-wide preparedness and response program partners decided to limit new proposals by coordinating centers and offices. Smaller coordinating offices were permitted one proposal each, while larger coordinating centers were permitted one proposal per national center and OD. COTPER will continue to follow this recommendation to review new proposals every year, but shift to reviewing ongoing activities every other year.

Discussion Points

A BSC member noted that the Board was probably most enthusiastic about the three-page concept paper and urged Dr. Lindsey to keep educating people. This is really not a matter of writing a proposal twice. It is doing a little bit of the work at the beginning and then only doing the extra work if selected as one of the top 10. The idea is to build on the concept paper rather than to repeat anything or do more work than necessary. Many other entities use this kind of process, and it really does save time. With respect to that twelfth recommendation, one of the Board's points was not just about the efficiency of not reviewing things that have to be funded twice, but also of not changing the guidelines and procedures every year. Board members heard a lot of complaints about this such as, "I'm so confused. I got used to this process one year, and it was radically changed the next year."

Dr. Lindsey stressed that she would continue to advocate for the three-page concept paper, and that she really did hear the stakeholders when they stated that the changes within COTPER's guidance occur every year. COTPER is passionate about improvement, and has already begun to implement that component.

Regarding the Top Secret clearance issue, a BSC member expressed concern about the restriction of information within an organization that is needed to sensibly run the organization. The response to that is not necessarily to get more people with clearances and classify more things. Instead it regards looking at products, considering how much of the threat information really is Top Secret, considering the sources of the information, et cetera. It does not stand to reason that the general area of information needed to write budget line items is really Top Secret information, and most of it could be found in any newspaper. CDC has a moral imperative and should be able to access information needed to do its job effectively. DHS has

classified the earthquake impacts for official use only, which makes no sense. This is an insidious process.

Dr. Besser responded that the PAHPA legislation included language for DHS to develop an unclassified threat assessment each year that could be used by the public health community and others. The information is not very useful if it is locked away somewhere. CDC does not have classification or de-classification authority, so the agency is at the beck and call of some of the groups that do. CDC has been pushing to make information available that could be used by public health at the state and local levels, among others.

Regarding the threat assessment issue, an *ex officio* member pointed out that some information is in the public domain. BARDA does their countermeasure targeting based on the material threat determination that DHS has the lead on, but they also conduct a health risk assessment and have a report that lays out the framework for their countermeasure development efforts that is tied to the material threat determination. Regarding the third recommendation to seek more input from outsiders, while it is true that FACA limits COTPER's engagement with outsiders, there are other processes through which such input could be garnered that would not trigger the FACA regulations.

Regarding the fifth recommendation, an inquiry was posed regarding what percentage of the proposals had partners outside of CDC but still within the federal government, and whether there were reasons why proposals were restricted to CDC participants.

Dr. Lindsey responded that every proposal is probably linked to a partner. For example, currently COTPER is funding the Office of Workforce and Career Development (OWCD) which has health scientists embedded as FTE's throughout the US. These health scientists are responsible for training the state laboratorians on current techniques for detecting biothreat agents. The Association of Public Health Laboratories (APHL) is the lead connecting partner because it is the national laboratory training network that is funded through that cooperative agreement.

Dr. Sosin clarified that Dr. Lindsey was speaking to a subset of COTPER funding in the fiscal allocation process. This is about the funds that go out to other parts of CDC their projects, although it is not the only work that is done and supported in COTPER.

An *ex officio* member asked whether there was any restriction on using this slice of funding to partner with another US government office that may be able to contribute additional funding.

Dr. Lindsey responded that this occurs in most of the coordinating centers and offices. They will perform a certain activity, and the seed funding provided by COTPER is leveraged with other funds from other federal agencies, such as the Environmental Protection Agency (EPA), DHS, and others. There are many federal collaborations and there is no restriction.

Regarding the security clearance issue, a BSC member thought that one purpose of having a particular security clearance level was to pass any scrutiny. However, not everyone needs to have clearance. Most groups have their own clearance services, so CDC needs to collaborate to figure out what CDC really needs to know and who really needs to address a certain piece. Perhaps CDC's in-house clearance group could offer some direction. Regarding the eighth recommendation and making exceptions because H1N1 is making everyone busy, there is really never a time when emergency preparedness is not busy. There is always something (e.g., hurricane, salmonella outbreak). It is not clear how to overcome busy times, but this must

be addressed. Should one person be left back? Are standards minimized during that period of time?

Dr. Lindsey agreed that especially in this work, no one really ever has time. She thought about tasking the deputy division director with this responsibility, because this individual tends to “hold down the fort.”

Regarding the intent of the security clearance issues, Dr. Sosin indicated that there was acknowledgement during the review process that at the back end, in the selection of the proposals, there is visibility of the classified information among the leadership group. What was being asked for was on the front end. That is, while priorities must be set without divulging classified information, the priority setting process needs to be better informed at the front end.

Dr. Lindsey agreed that their frustration was going through Stage 1 in which the priorities were set without having the information needed to set the priorities. This risks missing the target with the guidance and the call for proposals.

Regarding the three-page concept paper, a BSC member pointed out that the advantage is that it really forces groups to focus in on the essence of what they want to do. The advantage for COTPER is that it can then read the pre-proposals and decide what direction they are really going in the request for proposal (RFP). While a group may not be selected, they will be much less depressed than if they had written a long proposal. However, if selected during the concept paper phase, when the full proposals are submitted, there will be a higher chance of funding because there has been a pre-selection process.

A liaison member wondered how this related to the overall mission of CDC in terms of funding states from the matching side. There are some programs for which states have matching funds and orchestrate budgets within the state to match that. There have to be allocations from state governments in order to match the programs being conducted. If they shift within the year, the matching funds are pulled back and there is less engagement by state elected officials. It has become problematic for states in trying to explain why programs are not working or why they were cut off. The duration of the cycle is also an issue. Most health officials this liaison had spoken with said that a three- to five-year cycle would be preferable. If a cycle is broken, but personnel are dedicated for training and hiring, this can affect the overall program because if people are lost in the middle of a cycle, there must be rehiring and retraining. This really wreaks havoc at the local health department level.

Dr. Sosin responded that all of those comments were absolutely relevant to the Public Health Emergency Preparedness (PHEP) cooperative agreement, and COTPER takes them seriously. The process to which Dr. Lindsey was referring regarded how CDC, as the strategic arm of preparedness for the agency, distributes resources within the agency to address priority issues. This is not about the priorities for state and local preparedness funding, although obviously there is a relationship that COTPER moves toward. However, it is not a legal or budgetary relationship through the PHEP.



Welcome from the CDC Director

Thomas R. Frieden, M.D., M.P.H.
Director, CDC
Administrator, ATSDR

Dr. Frieden bid those present a good afternoon, indicating that he was delighted to join them. He reminded everyone that COTPER provides a platform for response throughout the agency, and reported that he had identified certain key priorities for CDC in the coming period. The first priority is to strengthen CDC's surveillance and epidemiologic systems. Clearly, COTPER has been very important in that and more needs to be done. Second is to improve CDC's ability to support state and local partners. Clearly, one of the key actions of COTPER is the Division of State and Local Readiness (DSLRL) and working with local and state public health agencies to increase their ability to respond to everyday challenges, as well as to emergencies. A third priority has been to strengthen CDC's work in global health. The influenza pandemic brings home how very important it is that CDC have effective units and platforms around the world to work with other countries, both to assist and to obtain information that is directly relevant for people here.

The fourth priority is to improve CDC's ability to affect policy in healthcare and other areas. In preparedness, there is clearly great importance to marry public health and the healthcare response. This is an awfully bad time to have had a pandemic, given that states and localities are broke. That comes after decades of under-investment in public health and in the midst of a healthcare system, to put it mildly, that is not optimally structured for coordination, rigorous use of information, and prevention—the things that are very important in influenza response. All of that means that the requirements on the state and local partners are even stronger, and one of CDC's key roles is to do everything it can to strengthen partners. COTPER has focused on accountability and collaboration, and values the feedback received from people outside of CDC, both in terms of feedback and in terms of guidance and science. Science is the basis for what CDC does. President Obama has said that science is about ensuring that facts and evidence are never twisted or obscured by politics or ideology. Dr. Frieden stated that he believes that perspective makes it possible to make rapid progress in all of the areas in which COTPER works.

The Emergency Operations Center (EOC) is the nerve center for CDC's response to H1N1 and is maintained by COTPER. Funds going out to state and local health departments are being augmented by more than half a billion dollars for influenza preparedness through COTPER. Regulatory oversight of select agents is a new area for CDC and one that is challenging. Consideration needs to be given to strategic thinking about what is going to make the most difference. Preparedness research is another area that is expanding. It is known that there are a series of information systems that are supported by COTPER funding. They are looking hard at what is really useful and what needs to be done to improve things further. Also through COTPER is the Career Epidemiology Field Officer Program. This is very important—putting people in the field, boots on the ground, helping shoulder to shoulder with state and local health departments.

Obviously, the work is a very wide range of things including guidance for healthcare practitioners, response to emergencies, protecting emergency departments from becoming overwhelmed, looking at issues like intensive care unit capacity and surge capacity, ensuring that there are adequate laboratory services, the lab being consistently the poor relation in clinical and public health practice all too often, and recognizing that CDC cannot do everything. Preparedness is also about prioritizing. CDC needs to make sure that the resources invested strengthen the agency, not only if an emergency comes, but also if an emergency does not come, to the greatest extent possible. They also need to look at areas like radiation safety, where there are important gaps in preparedness at the national, state, and local levels that could be filled.

Dr. Frieden concluded that he was really looking forward to learning about the interactions with the BSC and their suggestions.

Discussion Points

Noting that public health works from a model of core functions and central services, a BSC member pointed out that on the preparedness side, they have been developing different models. It appeared that one of the areas in which CDC could play a key role was bridging the core functions paradigm and preparedness paradigm such that they had the same basic messages—that carrying out core functions and central services is really about health departments being prepared to do their jobs. If the organizational units within CDC could begin to look at better ways to increase the communication between the traditional public health fields and the preparedness fields, and how to put these various conceptual models together, that would be a real step forward.

Dr. Frieden agreed, stressing that preparedness is one of the core public health functions. The next phase is to define what within preparedness is core and then to begin assessing against that.

A BSC member requested that Dr. Frieden share anything he could in terms of the direction that the CDC reorganization would take with respect to COTPER or general emergency preparedness work within CDC.

Dr. Frieden responded that if organizations do not change and evolve, they have problems. CDC's challenge is to establish a structure that is efficient, effective, and makes optimal use of the skills available throughout the agency, which are substantial. At this point, consideration is being given to the big blocks rather than the small blocks. One challenge, obviously, is doing this in the midst of an emergency response to H1N1. Some people have suggested holding off on any organizational change until after the influenza season. The problem with that is that the reason for organizational change is that there are some things that are not as functional as they need to be to function effectively as an agency. Therefore, while they may not make all of the changes that they would have otherwise made absent H1N1, he thought it was even more important to make many of the changes. He did not foresee significant changes in the COTPER role. The name may be something that people have thought about before, so maybe somebody has thought about again, but that is far from substantive. The broader issues in the organization have to do with ensuring just what he outlined earlier—that they must have the best possible data, data systems, data analysis, and data presentation through epidemiology and

surveillance, and that they further strengthen their ability to support states and localities. Here, COTPER has a very important intersection with some of the things that CDC is doing, but he did not foresee any other significant organizational or structural changes. One very important issue is that CDC is recruiting for the new director of COTPER. He expressed his gratitude to Dr. Sosin for his leadership during this time. There is a national search underway, inside and outside the organization, to find the best possible person for that role.

A BSC member noted that they speak of the states and localities as emergency management preparedness, but often the inference is a homogeneous mass "out there," though they know it really is not. As shown with Hurricane Katrina, there are weak links in the emergency management. These weak links are even more devastating at the local level than they are in some other aspects. With that in mind, this member wondered what role Dr. Frieden saw CDC playing in identifying the organizations that are the weakest links and that are the least likely to be fixed with funding, given that they do not have the ability to manage and spend it.

Dr. Frieden responded that the first issue is identifying the areas, and then developing a plan for helping them get stronger. Health is fundamentally a state responsibility, so it partially has to do with working with the state and local political structures to ask if there is something CDC can do about this. The existence of direct assistance or Career Epidemiology Field Officers, high quality effective CDC staff who can sit in a state or locality to help build the system, cannot resolve all of the problems, but it can be extremely important. Thinking more broadly about further strengthening, also essential is the training that CDC does for leadership of state and local health departments and the resources the agency provides in terms of money, technical support, guidance, and input. Many times people feel it would be easier just to do it themselves, but that is not an option, so the challenge is for CDC to work effectively through its many partners. That means having a very effective structure, including people at the agency who know what it is like to get the job done in the field.

A BSC member noted that one of the things Dr. Frieden mentioned in passing in his list was a topic that was raised during last year's BSC meeting regarding radiological nuclear preparedness. There was an Institute of Medicine (IOM) workshop report published a few months previously that was very pivotal in terms of describing some of the medical disaster responses for a nuclear detonation. With that in mind, Dr. Frieden was asked whether he could say anything more specific about the strategic directions or initiatives on the horizon for CDC and the preparedness activities.

Dr. Frieden responded that this is still under definition, though he identified that an important issue with radiological dispersal devices (RDD), radiological emergencies being important, primarily in terms of the economic dislocation that they can cause and the potential that they would be sourced from the medical field. In terms of an improvised nuclear device (IND), it is important to relook at what is now viewed as collective from the 1950s in terms of fallout shelters, but actually for which there is pretty good science and thinking about simple ways of monitoring if it were to happen: What has been the trajectory of radiological contamination? What should be the duration of time of sheltering in place? What should be the route of evacuation? While this is very straightforward, it probably needs to be done.

A BSC member expressed appreciation for Dr. Frieden's recognition that public health has been under-funded for a long time, and that to some extent the low severity pandemic helped to identify gaps that need to be fixed. The Department of Defense (DoD) struggles with how to use the lessons learned and the gaps discovered to improve foundational public health.

Dr. Frieden responded that one of the challenges is that it is very difficult to obtain resources for core public health functions. Many of them come from states and localities where it is particularly difficult. This is difficult to sell to people who make financial decisions. They need to use every opportunity to make the point that they can only respond if there is a structure in place. It is sobering to recognize that they are fighting hard in health reform for \$10 per capita per year for prevention when \$7,000 per capita per year is spent for treatment. Even that \$10 in some ways is going to be a long shot to get approved. The emphasis on prevention is inadequate. They also must ensure that any funds received are well spent in order to document merit in the trust the public and policy makers place in them to make good use of public funds.

A liaison member thought Dr. Frieden made a very profound statement about the perception of public health in general. This individual pushed a bill through a state to widen the scope and the definition of public health, because as statutes are written, this is very narrowly defined. Many times it is basically about quarantine and isolation—1800s language. Dr. Frieden was asked to comment on whether anything could be done with the movement to change the healthcare system in terms of restructuring the framework of public health.

Dr. Frieden responded that if public health is perceived as integral to health reform, as broader than health care reform, then they would have a chance of getting the kind of resources and authority that would be needed to engage in prevention much better than is currently done. Prevention is on the map today as it has never been before. The challenge is to use this opportunity, use resources well, monitor well, and support partners well in order to make substantial differences and demonstrate that the investment is worth it.

Dr. Sosin thanked Dr. Frieden, emphasizing what a pleasure and honor it was to have him present during this BSC meeting to hear perspectives and answer questions. COTPER has a broad and unique membership, and is very excited about their breadth and multi-disciplinary function. COTPER looks forward to more interactions with Dr. Frieden around the BSC's guidance and recommendations.

Dr. Frieden thanked the BSC members for taking time out of their busy schedules to assist CDC.

BSC Peer Review Status Reports

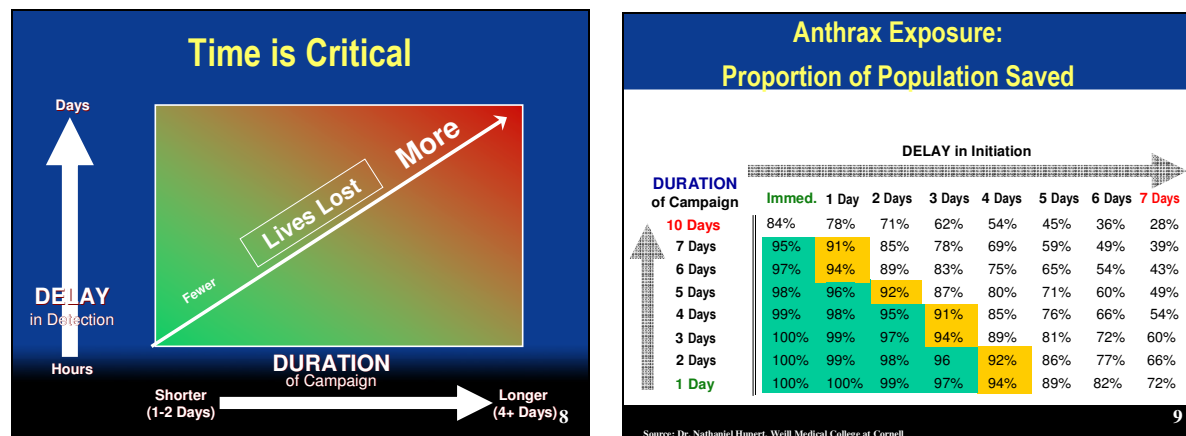
Division of Strategic National Stockpile (DSNS)

Susan E. Gorman, Pharm.D., M.S., DABAT
Associate Director for Science
Division of Strategic National Stockpile
Coordinating Office for Terrorism Preparedness and Emergency Response

Dr. Gorman began by recognizing Dr. Jack Muckstadt. On behalf of COTPER and the division, she expressed appreciation for his enthusiastic leadership as chairman of their expert panel. She reported that DSNS's expert panel was made up of the following many diverse membership: Jack Muckstadt, PhD, Chair, Industrial Engineering / Mathematics, Cornell University; Aruna Apte, PhD, Operations Research / Mathematics, Naval Postgraduate School; Margaret Brandeau, PhD, Engineering-Economics Systems, Stanford University; Patricia Kelly, MBA, MS, Logistics, Logistics Management Institute; Steven Mier, MPH, Public Health /

Emergency Response, Mier Consulting Group / University of Minnesota; Kenneth Sturrock, MA, MPH, Public Health / Emergency Response, Florida Department of Health (former regional emergency response advisor).

The scope of the DSNS review was a focus on comparison of the current strategic national stockpile (SNS)'s hub-and-spoke model for inventory storage and delivery versus a more forward deployment of assets in a Cities Readiness Initiative (CRI) inhalation anthrax-related event. In the current SNS hub-and-spoke model, the majority of DSNS's assets are centrally located in various portions of the US, and would be delivered to the site of a national emergency. They are not spread out in every state currently, and DSNS is considering whether to forward place additional assets in a CRI anthrax-related event. The CRI is a federal initiative that began in 2004, which is part of the PHEP cooperative agreement, with 72 CRI cities designated in the US that currently include 57% of the US population. The CRI planning scenario is based on a release of aerosolized anthrax over or throughout a major US population center. US intelligence assessments indicate that a large-scale anthrax release is possible with existing terrorist organizations. Also known is that standard microbiological procedures could be used. Nothing fancy is required, and an aerial dispersion of anthrax over a large geographical area is possible using commercially available equipment. Upon receipt of material from DSNS, the affected metropolitan area must rapidly distribute and dispense life-saving medical countermeasures within 48 hours. This is a major undertaking. Consequently, DSNS must be able to move all of the medical countermeasures to the affected area within 12 to 24 hours. The following figures illustrate that time is critical:



Any delay in the detection of an event and any longer duration of a prophylaxis campaign will result in more lives lost. Another way of looking at this based upon these graphics is that if a prophylaxis campaign takes 5 days, and it takes at least 2 days to start that campaign, an 8% mortality rate can be anticipated in the affected population. This model was developed by Dr. Nathaniel Hupert of Weill Medical College at Cornell.

The expert panel was presented with the following four specific review questions:

- 1) Assuming a community can begin forwarding material to their Points of Dispensing (PODs) at hour 12 after making a request, is the current hub-and-spoke model adequate for responding to a CRI event?
- 2) If the community can begin using material at 3, 6, or 9 hours after making a request, and taking into account the 72 CRI cities and their populations along with the requirement to

respond to simultaneous events in three cities, how much material should be forward deployed and in what locations?

- 3) What are the pros and cons associated with procurement of additional inventory, storage locations, manpower needed to manage storage locations, perform annual inventories, and provide security, and the potential need for movement of material from multiple locations to one location where it may be needed?
- 4) Would there be other more efficient alternatives to the hub-and-spoke model in a CRI event?

Regarding the general assessment methodology, the workgroup engaged in an extensive review of background materials that were provided to them in advance (e.g., fact sheets, evaluations, guidance documents, papers, videos, past presentations, legislative, and miscellaneous information). They were also provided with focused review questions surrounding the four main questions that they had time to think about and answer before convening. Those responses were non-attributable, were combined and compiled, and were given to all the work group members so that they could review the responses of the entire group. There were also two pre-meeting webinars, the first of which focused on an overview of the SNS and the Logistics Branch and its functions, and the second of which focused on the CRI so that the work group would have a better understanding of why the questions were being posed. Presentations were given during the meeting itself from state and local stakeholders, on current modeling efforts, and on SNS technical assistance.

Significant milestones include the following:

- ☐ Pre-meeting webinar #1 conducted April 17, 2009
- ☐ Pre-meeting webinar #2 conducted July 17, 2009
- ☐ Workgroup meeting convened July 28-30, 2009
- ☐ Draft report produced July 30, 2009
- ☐ Edits and additions of appendices to draft report ongoing
- ☐ Findings to be reported to full BSC in April 2010

DSNS experienced a number of successes with its program evaluation. DSNS and COTPER leadership was very open to the review process, and was very interested in hearing the panel recommendations. The panel members interacted very well with the program staff and the speakers, and they asked a lot of questions during the question and answer sessions. There were many insightful and fruitful discussions among the panel members alone, as well as with the COTPER and DSNS staff. Most of the background materials had been previously developed, which was very good for this program. Nevertheless, there were some challenges. The meeting had to be postponed initially due to the H1N1 response in April 2009. Although the meeting was to be convened in early May 2009, it was postponed until July 2009. They were thankful that everyone was still able to participate. While the group did not have any problems maintaining the focus of the panel to the scope of the review, discussions regarding points of dispensing were limited due to running out of time. The focus had to be narrowed to the four questions, which is fairly typical with any workgroup. They realized after three days of discussions that there is a lack of available data to answer all of the four questions posed to the workgroup. Specifically, there is limited data available regarding how soon states are able to use the assets sent to them by DSNS, how quickly they can mount their points of dispensing, and how quickly they can actually begin dispensing prophylaxis. As with any new

implementation or recommendation, there are staffing and funding considerations that need to be taken into consideration, depending upon the actual recommendations.

Discussion Points

If there is not enough data and they are unable to make concrete recommendations, a BSC member wondered how the lack of data would be handled.

Dr. Muckstadt responded that the recommendations they are focusing on is the process that needs to be undertaken in order to answer the questions, along with some very detailed ways in which the process should be executed. They also recommend that this be continued subsequently so that they can actually answer the questions.

Dr. Gorman added that once they obtain the necessary data points, they can certainly go back and answer the four questions.

A BSC member pointed out that the model considering the delay of initiating the dispensing of the SNS has a number of days in it. Considering this from the standpoint of areas of the country that have aerosol detection ongoing all of the time versus the areas of the country that do not have aerosol detection ongoing, this member wondered whether there are days that precede the two days for initiation of the SNS distribution. That is, do greater delays have to be considered based on detection delays that will occur both in cities and in rural areas?

Dr. Gorman responded that she was not sure she could fully answer the question; however, she assumed that there were days before the actual detection, so that model looks at two days after the detection. There are obviously going to be days previous to that during which something was occurring about which they were not aware.

Dr. Sosin added that clearly they are setting the bar and driving toward that bar. COTPER would like the bar to be even lower, and acknowledges that even in best circumstances in which the decision to deploy happens concurrently with aerosol detection in the environment, there is going to be loss of life and negative impact of those events that cannot be prevented. The CRI initiative bar is one that is a stretch still, but is not being refined for all of the nuances that affect the impact of the response.

An *ex officio* member asked for clarification regarding whether there was insufficient data specific to anthrax and distribution of countermeasures for anthrax, or if there were data from other events that they could draw upon to extrapolate into this specific agent. If not, it would seem beneficial to design an exercise that might generate helpful data.

Dr. Gorman responded that the data are lacking regardless of the organism, although they were focusing on an anthrax inhalation event in a CRI scenario. They are just starting to get some data points through exercises with the states and cities and having them collect that information.

Regarding the course of action analysis, a BSC member asked whether they were just looking at the 72 cities or if there would be an analysis based on geographic region—perhaps that it might be 30.

Dr. Gorman responded that the focus of this review was the CRI events in those 72 cities with respect to being able to prophylax their entire affected population within 48 hours. After those questions are answered, the scope can certainly be expanded.

A BSC member inquired about the shelf life and restocking required of the materials in the stockpile, and how that influenced the restocking demand and the ability to push things out further or concentrate more in the hub.

Dr. Gorman responded that generally, oral tablets have a 2- to 3-year shelf life, but because they are maintained under federal control and temperature monitored, they can be entered into the Shelf Life Extension Program, which is administered by the FDA. Through this program, the FDA tests the stability, integrity, and purity of the product and assigns it a new shelf life if it passes all of the required tests for re-labeling with a new expiration date. However, some other activities encroach upon that. The FDA has now said that those units that would be labeled "For SNS Use Only" that might have gone through the Shelf Life Extension Program would now have to be used under an Emergency Use Authorization (EUA) because the labeling is a deviation from the approved labeling that the company supplied to the FDA when they submitted their new drug application. Having to use a product under an EUA results in an added layer of time. They could forward deploy products even if they had to be used under an EUA because they would be maintained under federal control. Shelf life starts as 2 to 3 years, but can be extended indefinitely as long as the product passes stability testing.

Division of State and Local Readiness (DSLRL)

Christa-Marie Singleton, M.D., M.P.H.

Associate Director for Science

Division of State and Local Readiness

Coordinating Office for Terrorism Preparedness and Emergency Response

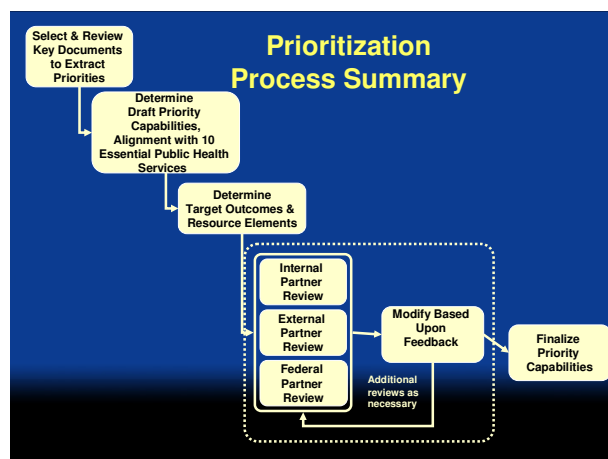
Dr. Singleton began by acknowledging the members of the DSLRL who were in attendance, as it reflected their support of this process and their enthusiasm for being part of the review. DSLRL's review topic area is the prioritization process for awardee preparedness capabilities, and the strategic management of the public health emergency preparedness program announcement. In order to conduct this review, DSLRL requested that experts assist them in thinking through two main areas: 1) project management / grants management because they are a funding arm of COTPER; and 2) public health practice / strategic planning because their funding affects state and local public health departments' emergency preparedness. The science office within COTPER has been able to successfully recruit outstanding members of DSLRL's upcoming workgroup, including the following members: Jack Harrauld, PhD, Workgroup Co-Chair, George Washington University / Virginia Tech, Systems Engineering; Ellen MacKenzie, PhD, Workgroup Co-Chair, Johns Hopkins School of Public Health, Behavioral Sciences; Harry Hatry, MS, Urban Institute, Project Management; Ricardo Millet, PhD Association for Study and Development of Community, Grants Management; Patrick Libbey, Former NACCHO Executive Director, Public Health Practice; Bonnie Arquilla, DO SUNY Downstate, Emergency Preparedness; and Karen Pane, MPA, RN, Department of Veterans Affairs, Strategic Planning.

With regard to the history of DSLRL and the PHEP cooperative agreement, in 1999 this funding stream was first established as a competitive grant program to address terrorism-related emergencies focused on bioterrorism. This funding was allocated to states that competed for the funds. In 2002, following the events of September 11, the PHEP cooperative agreement was established in the reorganization of emergency preparedness funds for public health. Seven focus areas were designated, with attention to bioterrorism. State and local communities that received this funding were targeting their efforts in areas such as preparedness planning, biological laboratories, radiological laboratories, risk communications, health work networks,

and education and training. In 2005, the preparedness program was reauthorized and reorganized toward an “all-hazards” focus. From 2005 and to date into 2010, annual activities, tasks, and requirements have been added by internal CDC and external (e.g., White House, Department of Health and Human Services) stakeholders. This situation has caused extreme disconnects between CDC, COTPER, and the PHEP awardees. At that time, the program announcement identified approximately 15 to 17 priority capability areas, but those areas may or may not have aligned with other emergency management capability areas. Additionally, there was a list of approximately 150 critical tasks, but the term “critical tasks” still created a disconnect for awardees because the agency may have identified them as a critical task, but the funding announcement itself did not stipulate that they were specific requirements. With this particular cooperative agreement, the only requirements for awardees was that they must submit a mid-year assessment, an annual progress report, and a status of their funding. The program has had questions about what is really required as initiatives, and political intents changed between 2005 and 2010, so those interests have been added to the cooperative agreement. Thus, there has been a shift in the focus in the program. The continual shift of focus has led DSLR to a point at which they want to embark upon a different way of organizing this funding stream. In 2006, PAHPA reauthorized the preparedness program and mandated a capability-based approach, which is why DSLR is now asking for this Board’s input with regard to how to determine capabilities and prioritize them for the PHEP.

The workgroup review is scheduled for September 15–17, 2009 in Atlanta. The scope of the review is to: 1) Evaluate and provide recommendations to the DSLR process for selecting PHEP cooperative agreement priority capabilities; and 2) Evaluate and provide recommendations to DSLR’s proposed approach to coordinate, organize, and manage the various CDC, US Health and Human Services (HHS), and partner stakeholders’ input in the management of future content for the PHEP cooperative agreement program announcement.

As noted by a previous speaker, DSLR has made the determination that public health and emergency preparedness lie at the intersection of two fields. The public health field has actively been known or associated with the taxonomy of the 10 essential public health services. The emergency management or emergency preparedness field has been largely aligned with DHS’s Target Capabilities List. The public health emergency preparedness field is somewhere in the middle. It is unclear whether that split is a 50/50, 60/40, or 90/10 split. Regardless, our hope is to better merge those fields in the program announcement. In doing so, the following is a schematic that represents how DSLR proposes to move forward for the next five years of this cooperative agreement and this program announcement:



DSLRL is currently selecting and reviewing key documents in the legislative arena—the legislative drivers, such as PAHPA; the Homeland Security Presidential Directives that address emergency management or public health preparedness; and partner documents that have addressed public health emergency preparedness. These documents are being reviewed to extract priorities that come from each. Those are then being aligned and adjusted with the target capabilities list from DHS and with the 10 essential public health services. Preliminarily, the intent and hope is to determine a way that if a set of prioritized public health capabilities is achieved, it will help state and local communities better attain the various 10 public health services. The target capabilities process in DHS is currently undergoing revision. The structure currently includes the capability, a set of activities, and a set of critical tasks. This process is under realignment to potentially have a set of targeted outcomes per capability, and targeted resource elements or capacity groups. For each priority capability, DSLRL intends to determine targeted outcomes, targeted metrics, and targeted capacities. One of the criticisms of the current cooperative agreement is that, as DSLRL attempts to define and measure preparedness at the state and local level, they need to determine what the target is. The SMEs will be engaged to help DSLRL think through what will determine the capabilities, what the target outcomes should be for those capabilities, and what the target capacities should be that build up to those capabilities. These lists will then undergo an internal review with CDC SMEs, an external partner review with DSLRL's state and local partners, and a federal partner review with HHS and DHS partners. This will be a cyclical process in which each time feedback is received, the lists will be reviewed and modified until a final set of prioritized capabilities is reached.

The questions for the DSLRL workgroup are as follows:

- ☐ What are the strengths of the proposed process for determining priority capabilities for the PHEP cooperative agreement?
- ☐ What are the weaknesses of the proposed process for determining priority capabilities for the PHEP cooperative agreement?
- ☐ Does the BSC have recommendations for improving the process for selecting priority capabilities for the PHEP cooperative agreement in order to advance state and local public health emergency preparedness and response?
- ☐ What alternative opportunities could be used to organize DSLRL's prioritized preparedness capabilities (in addition to or in place of the 10 Essential Public Essential Services for Public Health) to advance state and local public health preparedness and response?
- ☐ What are the strengths of the proposed DSLRL PHEP cooperative agreement change management board to coordinate, organize, and manage the various CDC, HHS, and partner stakeholders?
- ☐ What are the weaknesses of the proposed DSLRL PHEP cooperative agreement change management board to coordinate, organize, and manage the various CDC, HHS, and partner stakeholders?
- ☐ What alternate strategies or approaches (in addition to or in place of a change management board) could be considered by DSLRL to improve the management of the various CDC, HHS, and partner stakeholders?

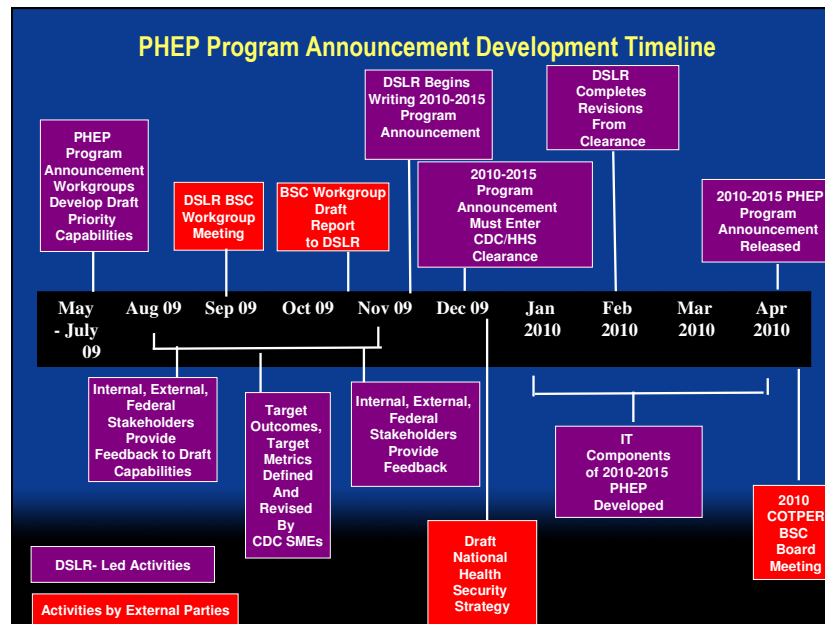
- ❑ In light of declining federal funds for the PHEP, emerging preparedness issues, and changes in stakeholder priorities, what actionable recommendations do you have for DSLR to advocate for the ability of its awardees to first fully develop and achieve a prioritized set of national public health preparedness capabilities?

Background documents to be provided to the workgroup prior to the review include the following:

- ❑ A Methodology for Prioritizing Public Health Preparedness Capabilities
- ❑ DSLR Development and Implementation of the 2005-2010 PHEP Cooperative Agreement
- ❑ Flow chart of the 2005-2010 PHEP approval process and role of significant stakeholder inputs to that process
- ❑ 2005-2010 PHEP cooperative agreement (initial Program Announcement AA154 and subsequent annual budget period continuation guidance 2006 – 2010)
- ❑ PHEP cooperative agreement legislative requirements and authorizations
- ❑ “State and Local Preparedness: Reality of Preparedness” (a draft white paper describing PHEP funding history and funding issues)
- ❑ DSLR’s Program Announcement Change Management Board Proposal

A major success for DSLR is that this very small division works extremely hard to manage the funds given to it as stewards for the state and local public health departments. There are challenges as well. The novel H1N1 influenza emergency funding that has come to DSLR’s doorstep recently has a competing priority for DSLR’s time. Members of the division are working late into the evenings and into the early morning hours to get this funding dispersed. One of the requirements of PAHPA is that DSLR’s funding stream must align with the National Health Security Strategy (NHSS) content. The challenge is that the NHSS is not yet available, and is not due to be released until December 2009. In order for DSLR to publish its announcement, the draft document must be completed by the end of 2009. PAHPA also mandates a capabilities-based approach and strongly recommends the use of the DHS TCL. That list is undergoing revision for Fall 2010, so again, DSLR will not be able to align with this. DHS has asked CDC to help think through at least three of the upcoming target capabilities, so CDC has visibility into the target capabilities of mass prophylaxis, isolation and quarantine, and epidemiology and surveillance, which most likely will align as core public health public preparedness priorities.

Another major challenge is that DSLR has an extremely short timeline to respond to the workgroup review, as illustrated in the following graphic:



The workgroup review is scheduled for September 2009, with a draft report, including revisions and recommendations within the following month. However, in order for the program announcement to be released by April 2010, it must enter the clearance process by December 2009. Moreover, the division will have to address elements with the public health emergency response funding. The aggressive timeline to complete this announcement, implement it, and manage the current operations of the division poses a significant challenge for DSLR.

Discussion Points

A BSC member inquired as to how much coordination DSLR has with the group doing the NHSS. In terms of the capacity issue, this member also wondered whether a scenario set was being considered for the scenario basis in DSLR's documents.

Dr. Singleton responded that DSLR has some visibility into the NHSS efforts. They understand that the primary contract groups have shifted gears, so DSLR has seen a draft of some initial thoughts. The initial thoughts appear to align thus far with the thoughts coming out of HHS regarding the NHSS. In terms of the capacity issues of the scenarios, two of the documents DSLR is reviewing address some of the 15 planning scenarios; however, they have not yet fully thought through how to address capacity issues. Given that it is unlikely for there to be a finished product this year from the NHSS, DSLR believes the change management recommendations the board gives them will be very helpful. It is DSLR's hope that they are on track with whatever is in the final strategy; however, if the strategy shifts, DSLR will have to shift as well. Having a sound change management process in place will help them to best address any changes that occur.

A BSC member requested information regarding how DSLR planned to interface with the National Association of County and City Health Officials (NACCHO) operational definition of the local health department, and the development of accreditation standards by the Public Health Accreditation Board. Given that the standards are based on services, the disconnect is that they are going back to organizational capabilities rather than community wide capabilities.

There must be some type of bridge between the development of accreditation standards for local health departments and how that impacts overall community readiness.

Dr. Singleton responded that they reviewed the operational definition of a local health department, and Project Public Health Ready that NACCHO uses because they have been made aware that many local health departments use that as an accreditation standard for preparedness. It has very clear metrics for preparedness, so the input of Project Public Health Ready is being factored into the prioritization process. DSLR is also reviewing the public health standards process (e.g., current tools, documents) to think through how to best align with public health services. DSLR recognizes the need for a merger, but it is not yet clear how that merger should be done. Many state and local health departments are steeped in the services, so this would help to advocate that agenda.

A BSC member noted that the mapped out process showed a clear mismatch between the timelines with DHS and the TCL. This member wondered how that coordinated with hospital disaster preparedness, and what kind of coordination or synchronization would be going on there and perhaps through the Assistant Secretary for Preparedness and Response (ASPR).

Dr. Singleton responded that within ASPR, the hospital preparedness program is on a slightly different timeline from DSLR. However, both programs use a capabilities-based approach, and both programs are moving toward a tiered capability approach. Someone prioritized hospital capabilities into Tier 1 and Tier 2, so DSLR is going to mimic that approach and have a Tier 1 and Tier 2. DSLR attended the hospital preparedness program meeting recently, so there has been a lot of dialogue between the two groups regarding what a capability is, how a capability is defined, and how to measure a capability. DSLR initially considered whether a capability in the hospital program should be discounted in the PHEP so duplication could be minimized; however, they have decided against that, particularly because medical surge is an area that crosses the entire public health and medical continuity. To say that it is only a hospital-based capability ignores community health centers, private physicians, and academic centers. More thought needs to be given to how it is defined and how it fits across the central services. Elements of it address workforce issues, response, et cetera.

Dr. Sosin stressed that there has been a lot of interaction regarding how to integrate and coordinate efforts. COTPER hears the message from its state partners about why this is so critical. There are many details beneath that that need to be synchronized and are being worked on, so it is fully expected that the new relationships being built will also be reinforced at the highest leadership levels.

A BSC member requested clarification about the purpose of the change management board and what its functions were anticipated to be, and whether it would be contracted management between the states and the federal government, or it would be seen as supplanting the authority of this Board.

Dr. Singleton replied that they wanted some type of governance or process to manage these changes because the cooperative agreement has had annual changes to it, and the true sense of a cooperative agreement in a program announcement, whatever is decreed in the initial year, should stay that way for the announcement term. The cooperative agreement from 2005 is 114 pages long, and has several shifts in topic areas that are not in the 2009-2010 version. There has been an extreme emphasis on different areas being added and changed. Thus, it was thought that the process of a change management board would help manage requestors who wanted to add new elements or delete some elements away, in terms of whether a change was essential or it could wait until the next funding cycle. The previous history is that every request was deemed as an emergency change and therefore added to the PHEP. There must be some means to stratify these changes and prioritize them to be addressed in a more systematic manner. The challenge regards how to best manage the change that occurs. In terms of the structure and function, this would be a committee similar to the BSC, but it would be comprised of internal CDC SMEs, HHS, and DHS.

Dr. Sosin added that another perspective from which to think of this was that anytime a program has a large amount of money, it is prone to priority changes, carve outs, and other requirements that make it challenging to manage that program from the recipient and administration sides. For example, although the solution is very different, the SNS was in a similar position 5 years ago when decisions would be made in a variety of places in closed rooms with no governing structure. It is imperative to have the right partners, the right inputs, and to achieve a common understanding. Regardless of the term used, the idea of the change management board is to help DSLR stabilize the process, and ensure that the right voices are being heard in the process making those decisions so that they are more manageable and more equitable.

One BSC member commented that they must be very careful in terms of the way they define the change management board. It appeared to be largely reactive versus proactive. However, such a board should be using the planning mechanisms in a positive way rather than as something to react to, whatever the problem du jour is (e.g., defining it more on the positive side).

Division of Emergency Operations (DEO)

Mark Wooster, Ph.D.

Associate Director of Science

Division of Emergency Operations

Coordinating Office for Terrorism Preparedness and Emergency Response

Dr. Wooster indicated that the focus of the DEO's review is going to be on CDC's Emergency Operations Center (EOC). The workgroup membership includes the following: Lead for DEO will be Mark Wooster, DEO's ADS; DEO Workgroup Co-Chairs (both BSC members): Lou Rowitz, University of Illinois at Chicago, Public Health / Crisis Leadership; and Bob Ursano, USUHS, Social / Neuroscience; and DEO Workgroup Members: Amy Kircher, DoD, Emergency Management; Bill Waugh, Georgia State, Disaster Policy; Steve Ostroff, PA DOH, Epidemiology; Vince Covello, Center / Risk Communication - Decision Science; and Phillip Padgett, Boeing EOC, Emergency Management and EMAP.

The anticipated meetings are to include the first DEO webinar on January 18, 2010. This will give the DEO an opportunity to provide the workgroup with an overview of the division, the operations team, the after action report process, and the concept of director's critical information requirements. The second DEO webinar is scheduled for January 22, 2010 and will be informational if additional information is required by the workgroup, or can be used as a closed session for the co-chairs to work with the working group. The actual BSC workgroup meeting is scheduled to be convened January 26-28, 2010, which will be the formal review.

The basic problem that the workgroup will be asked to address pertains to the bridging of three cultures: public health response, public health practice, and public health science. In terms of the cultures within CDC and EOC, often issues that are expressed are cultural values that other groups do not understand.

With respect to the scope of this peer review, the objective is to evaluate CDC's current procedures and criteria for the utilization and activation of the CDC EOC for public health incident response. This has been broken down into four broad focus areas, which are to: improve and increase EOC utilization and activation, improve EOC coordination, improve the Director's Critical Information Requirements (DCIR) concept, and improve EOC policies and procedures. Under each broad focus area, there are the following additional questions that continue to be refined.

Improve and Increase Utilization and Activation:

- ☐ Utilization: What are the barriers to utilization of the EOC?
- ☐ Activation: What are the barriers to the activation of the EOC?
- ☐ EOC Facilities: What changes can be made to the EOC facilities and work environment?
- ☐ EOC Internal Procedures & SOPs: What EOC internal procedural changes need to be made?
- ☐ EOC Services: What services should the EOC offer?

Improve Coordination:

- ☐ Communications: How can the EOC improve communications?
- ☐ Training: How can DEO improve training for EOC stakeholders?
- ☐ Exercises: How can exercises be used to improve coordination?
- ☐ Deployment Coordination: How can deployment coordination be improved?
- ☐ Metrics: How can DEO and the EOC measure coordination success?

Director's Critical Information Requirements:

The DCIR is a framework to address the age-old problem regarding what to tell your boss, what not to tell your boss, and when. For example, should there be an immediate telephonic notification to the CDC Director between the hours of 0700-2200, email otherwise, for the following scenarios:

- Report all confirmations of new variant H1N1 influenza cases.
- Report any laboratory result indicating a virus more transmissible in humans than the current virus.
- Change in international response actions or strategy
- Change in international / state travel restrictions / guidance
- When WHO changes "pandemic phase"

These are what the director communicates to the rest of CDC. This framework also allows SMEs or others to communicate to the director what they think may be important, but it is a procedure for coordination and prioritization of information. The EOC would like the working group to assist them in assessing the information prioritization frameworks, reviewing other frameworks that may exist, in order to prioritize information as it flows into the EOC. The questions for this broad focus area include the following:

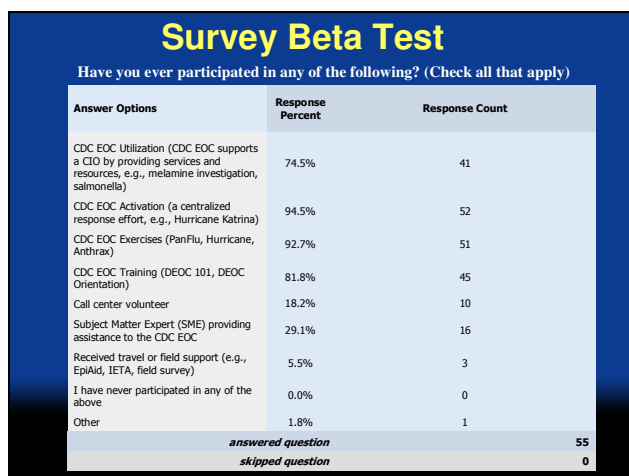
- ☐ Information Prioritization Frameworks: How should incident information be prioritization?
- ☐ Other Frameworks: What other available prioritization frameworks might be considered?
- ☐ DCIR Strengths & Weakness: What are the strengths and weaknesses of CDC's current DCIR framework?
- ☐ Information Flow & Action Triggers: How do we improve information flow and action triggers?

Improve Policies and Procedures:

The next broad focus area is improving policies and procedures in terms of the agency's higher level documents, such as after action reports.

- ☐ Policies and Procedures: What improvements could be made to CDC policies, plans, and procedures?
- ☐ After Action Reports (AAR): What improvements could be made to CDC AAR procedures?
- ☐ Communications: How can the EOC better communicate policies, processes, and procedures?
- ☐ Feedback: How do we increase stakeholder feedback on CDC EOC utilization/activation?

All of the questions in these broad focus areas will be refined to make them more specific. In order to help answer these questions, there is an internal stakeholder survey to be conducted. The purpose of the survey is to provide the BSC with feedback and viewpoints on the review objectives from the broader CDC community. The estimated distribution is roughly 3,000 individuals. The anticipated rate of return is 25%, although we would be happy with 10% to 15%. There are four separate surveys, one for each of four cohorts: Leadership, Emergency Coordinators, Subject Matter Experts, and Volunteers. There are individuals from the CDC community who volunteer during responses or exercises to sit in the EOC and perform various functions. The survey has been beta tested within the DEO. The survey is expected to be distributed via email on August 12, and will close on September 4. The analysis is expected to be completed by November 1, the draft report reviewed and vetted by December 1, and the survey tool and results presented to the BSC workgroup on January 26, 2010. Some of the results from the beta testing are as follows:



In terms of the documents DEO will be providing (e.g., after action report plans and policies that currently exist at CDC), these documents fail to capture what the EOC does 365/24/7. Some of the DEO BSC documents under development include the following:

1. Consolidated Report on Exercise/Incident Participation by CO/CC/I, 06-09
2. Consolidated AAR Report on EOC Utilization & Activation, 06-09
3. Consolidated EOC Utilization Report, 05-09
4. EOC Facilities Improvement Report, 2006-09
5. CDC's Deployment Coordination Program Responding to Stakeholders
6. EOC "call centers" and the evolution of "utilization" of CDC EOC
7. Virtual CDC EOC Development Project
8. CEUs and EOC Public Health Exercises
9. DCIR Policy Statement/Concept Paper
10. Consolidated LST report for 2006-2009
11. DEO's SA – Providing Essential Information

In January 2010, CDC stakeholder panels will be convened. The purpose is to provide presentations and receive questions from the BSC workgroup during the January 26-28, 2010 meeting. There will be 6 panels, one for each of the four focus areas plus SMEs and EOC Watch Staff Duty Officers. Each panel will consist of 4 to 5 members, with a stakeholder panel chair. The timeline selection and socialization of members is that stakeholders (primary and alternates) will be identified and vetted through DEO and COTPER. Save-the-date invitations will be sent out on November 1. Letters of instruction, presentation assignments, and alignment questions will be sent to panel members on December 1. Invitation to the January 18 and January 22 webinars will be sent out on December 1. Follow-up emails will be sent to stakeholders and selection of alternates on January 2. The results of the 6 panels will be presented at the BSC workgroup meeting on January 26-28, 2010.

There are a number of challenges and tasks. Time is a major issue, particularly with respect to having to work around the H1N1 response and possible hurricane responses. Although January 2010 seems far away, it is not. In addition, development of products in a dynamic environment can be challenging and coordination is critical. The need to develop the documents "de novo" will be tough, as will communicating the intent to the BSC workgroup and stakeholders.

Discussion Points

Regarding science, a BSC member noted that with the workgroup approach, they had created a research orientation to evaluating EOCs that can be applied to state and other EOCs as well.

Having worked with EOCs for a long time, a BSC member pointed out that they are an obvious success in two critical areas: the convergence of skilled people and the technology to support those people provides the ability to obtain an operating picture—a common understanding of situational awareness. However, there remains a woeful lack of ability to coordinate various EOCs (e.g., EOCs, joint field offices, HHS, DHS, FEMA), particularly given that there is so much differentiation between the EOCs. Is DEO dealing with that or at least coupling with HHS in this effort?

Dr. Wooster responded that this had to do with the different cultures in each EOC. Assessing cultural values and interpreting the way each EOC operates is part of the coordination of the whole EOC effort (e.g., understanding their drivers, their culture, and information flow requirements).

Regarding the surveys, a BSC member stressed the importance of making sure the results are well-summarized so that the real issues emerge. In addition, the questions need to be narrowed.

Dr. Wooster replied that it will be challenging to develop an analysis plan that is cogent, understandable, and usable for the workgroup. They do plan to narrow the focus of the questions.

A BSC member requested clarification about what constituted “internal stakeholders,” and whether there would be a link to the Secretary’s Operation Center.

Dr. Wooster responded that this meant internal to CDC. It is not in the plan for this particular review to address the Secretary’s Operation Center. This is designed strictly for CDC internal stakeholders.

A liaison member requested clarification about whether states were to raise their questions with the EOC.

Dr. Wooster replied that this was correct and that the EOC runs 365/24/7. The EOC also shares information back with the states. For example, if a physician has an issue that the EOC feels state public health representatives should know about, EOC deals with the physician and loops that back to inform the relevant state or territory.

A liaison member suggested assessing how well that system is working for those on the outside. It also needs to include two tiers: routine daily issues and non-routine issues like H1N1, given the differences in these scenarios.

Dr. Sosin acknowledged that there was some anxiety in the programs about the scope, the level of work, being reviewed by others, et cetera. There have been really good experiences in the initial reviews, which is very important. As each division or program goes through this, it is really changing the dynamic in many ways. He encouraged and urged the gentle but firm approach. It is important to conduct the right review, with critical and priority questions to be addressed. However, there must be a broad understanding that these must be kept in focus

and scale. He agreed that it was important to assess whether outsiders were getting the answers they needed in a more timely manner, with fewer interim calls and less incorrect information. Feedback is important in order to make any necessary adjustments. However, a program review is not the only way to obtain feedback, and he encouraged everyone to reach out within their professional organizations and to provide feedback.

A BSC member agreed that even though this is not an external review at this point, they must be cognizant that the perception and what happens externally is going to affect SOPs and who is placed in the EOC. The actions CDC takes internally will be affected by what is being requested or is needed externally.

Dr. Wooster replied that clearly, the whole purpose of the EOC is coordination and communication. The external part of that is also important, but there must be some focus to the review. The focus and refinement of the questions for an internal process is necessary for the immediate review, but in the coming years they could assess external stakeholders.

COTPER Program Updates

Preparedness Emergency Response Research Centers (PERRCs)

Mildred Williams-Johnson, Ph.D., DABT
Director, Extramural Research Program Office
Office of Science and Public Health Practice
Coordinating Office for Terrorism Preparedness and Emergency Response

Dr. Williams-Johnson expressed her gratitude for the opportunity to present to the BSC about preparedness research, and specifically about the Preparedness and Emergency Response Research Centers (PERRCs) funded through COTPER. Because this was the first time that the Board had heard about this program, she wanted to spend time giving them some background on its origins, inceptions, and the purpose of the program as it was shaped in COTPER.

This program is part of the Centers for Public Health Preparedness (CPHP) as called out in the legislation of PAHPA enacted in 2007. PAHPA called for the ASPR at HHS to consult with public and private entities to define the existing knowledge base for public health preparedness and emergency response, and to establish a research agenda based on priorities at the federal, state, local, and tribal levels to address public preparedness capabilities; and after having done so and identified the gaps thereof, to establish a research program to conduct public health preparedness and response systems research. One of the most important aspects of that legislation regards what is meant by public health systems research. What did Congress intend for us to do and how to go about doing it? This is a fairly recent area of research and as such, it has its origins in health services research field, but is somewhat different in looking at public health systems.

Glen Mays from the University of Arkansas defines public health systems research as “A field of study that examines the organization, financing, and delivery of public health services within communities, and the impact of these services on public health.” However, for the purposes of preparedness and response, COTPER expanded this definition somewhat in 2008 to better address PAHPA, “Public health systems are the constellation of individuals and organizations in the public and private sector that provide information and assets to promote population health,

provide health care delivery, prevent disease and injury and include health care providers, insurers, purchasers, public health agencies, faith-based organizations, and entities that operate outside the traditional sphere of health care. Public health systems research investigates the functions, operations, structure, and interactions of these public health systems.”

With respect to why public health systems should be a part of a research agenda for preparedness, more than \$7 billion in funds have been infused through various federal programs into state and local preparedness activities over approximately the last 10 years. A mechanism is needed to understand what has been accomplished to date in terms of public health preparedness capabilities and capacities, as well as what areas need improvements. A rigorous and systematic investigation is needed to quantitatively describe the complex system, identify gaps, and apply research findings to affect policy and programmatic improvements. As a young field, public health systems research is an area that can foster an innovative approach to addressing this research question.

To assist COTPER in defining the research priorities in the near-term to address PAHPA, COTPER charged the IOM to provide recommendations regarding research priorities for emergency preparedness and response in public health systems specific for the expertise in schools of public health; and to identify opportunities and 3 to 5 top-priority research areas that will result in measurable outcomes and near-term impact over the next 3 to 5 years in order to demonstrative impact on public health practice after funding these centers.

To this end, the IOM quickly stood up and convened a committee of academicians and practitioners with knowledge and expertise in emergency preparedness and response; conducted a public meeting and workshop to obtain expert views on research priorities in emergency preparedness and response for public health systems; considered research areas articulated in CDC’s report *Advancing the Nation’s Health: A Guide for Public Health Research Needs 2006-2015*; and identified priority research areas likely to result in “measurable outcomes” and “near-term impact” over the next 3 to 5 years. The resulting report, available online, is titled *Research Priorities in Emergency Preparedness and Response for Public Health Systems*. This is a letter report that was delivered to CDC in January 2008.

COTPER identified from that report four areas of recommendations for research to: enhance the usefulness of training; improve communications in preparedness and response; create and maintain sustainable preparedness and response systems; and generate criteria and metrics applicable to an all-hazards approach to preparedness to measure effectiveness and efficiency. These recommendations were used for priorities in the development of a research funding opportunity announcement, which would use a public health systems research approach to strengthen and improve public health preparedness and emergency response capabilities to: respond to the Congressional intent of PAHPA; initiate a public health research enterprise; improve capability assessment for emergency response and knowledge-to-practice; improve system performance for all-hazards over a scenario- or agent-based system performance; and leverage the academic research environment at schools of public health to accelerate the development of research methods, standards, best practices, and templates to improve systems for public health preparedness and emergency response. In the announcement, the research was to focus on public health preparedness and emergency response as content for the research; define systems research in the context of addressing public health preparedness and response capabilities and functions; assess the management of public health material, personnel, information supply chains, within the context of the complex and dynamic changing system of response and preparedness; and use an interrelated, interdependent, and multidisciplinary approach for the research.

Within the funding opportunity announcement, the purpose for conducting public health systems research on preparedness and response capabilities was defined as stated in PAHPA.

COTPER chose a Research Program Project Center Grants (P01), which is a unique grant mechanism that calls not only for center-based research, but also calls for that research to be interrelated and interdependent to address a specific objective or research theme. Priorities for funding consideration were based upon the recommendations from the IOM described earlier, and are to: enhance the usefulness of training, excluding formative and summative evaluation studies, such as training evaluation, program evaluation, needs assessment or analysis; improve communications in preparedness and response; create and maintain sustainable preparedness and response systems; generate criteria and metrics applicable to an all-hazard approach to preparedness to measure effectiveness and efficiency; and address cross-cutting themes (e.g., vulnerable populations and workforce themes, legal and ethical issues, and emergency preparedness and response in rural communities).

Regarding progress in the program, in FY 2008 COTPER developed this funding opportunity announcement in record time. As a result, 21 applications were received with 3 to 5 full R01 type research projects in addition to an administrative core. They were able to award 7 of those applicants for a 5-year program. At that time, the average award was \$1.6 million for each center for each year over the 5-year project period. Within those programs, there were 7 cores, with each center having its own administrative core, with unique functions to also have an advisory committee supporting that research effort to include a variety of participants (e.g., public health practice community representatives and organizations throughout the state or local communities), and efforts to foster pilot research and develop new investigators to address public health preparedness research activities in the future to grow the field of preparedness research. As a result of the funding in 2008, COTPER was able to support 27 R01 level research projects across all of these 7 centers. Within a given center, those projects are interrelated and interdependent in alignment with using the P01 mechanism. This is achieving synergy with those research projects as opposed to an additive effect for the research. The research collectively was greater than the total of the sum. Across the research centers, many of the projects are multi-faceted, but they all have a specific research focus for the research priorities that we identified, as noted here.

Research priorities addressed by the PERRCs funded in FY 2008 were as follows:

- ☐ Enhance the Usefulness of Training
 - *University of Minnesota: Simulations and Exercises for Educational Effectiveness*
- ☐ Improve Communications in Preparedness and Response
 - *Northwest Preparedness and Response Research Center*
- ☐ Create and Maintain Sustainable Preparedness and Response Systems
 - *Emory Preparedness and Emergency Response Center*
 - *Mental and Behavioral Public Health Systems Preparedness Research*
 - *North Carolina Public Health Preparedness Systems Research Center*
- ☐ Generate Criteria and Metrics Applicable to An All-hazard Approach to Preparedness to Measure Effectiveness and Efficiency
 - *Linking Assessment and Measurement to Performance in Public Health Emergency Preparedness Systems (LAMPS)*
 - *University of Pittsburgh Preparedness and Emergency Response Research Center*

Cross-Cutting Research Priorities Addressed by the PERRCs funded in FY 2008 included the following:

- ❑ Vulnerable populations and workforce themes
 - *Mental and Behavioral Public Health Systems Preparedness Research*
 - *Emory Preparedness and Emergency Response Center*
 - *Northwest Preparedness and Response Research Center*
- ❑ Legal and Ethical Issues
 - *University of Pittsburgh Preparedness and Emergency Response Research Center*
- ❑ Preparedness and Response in Rural Communities
 - *Northwest Preparedness and Response Research Center*
 - *University of Pittsburgh Preparedness and Emergency Response Research Center*
 - *North Carolina Public Health Preparedness Systems Research Center*
- ❑ Community Involvement
 - *Northwest Preparedness and Response Research Center*
 - *Mental and Behavioral Public Health Systems Preparedness Research*

In FY 2009, after funding these seven centers, COTPER convened the first grantee meeting to bring all of the centers together to discuss unique program planning activities and to learn about all of the research underway across the PERRCs. To further foster collaboration across the research, COTPER conducted webinars for all of the research projects. Some of the research centers were selected to participate in the opening session of the 2009 Public Health Preparedness Summit in San Diego. The intent was to share with the practice community these ongoing research activities, to discuss how COTPER views this research, and to begin to engage the practice community in this research enterprise. All of the research centers have an advisory committee, and they are strongly encouraged to engage their local and state health departments. All of them have done so. Not only was the summit an opportunity to explain this research to a national audience, but also it was an opportunity for the audience to provide feedback to COTPER regarding the impact of this research and how the findings can be translated into practice. In addition, COTPER conducted a workshop with some of its key preparedness partners, including some of the liaisons to the BSC, to begin discussions regarding how to translate the findings from the program to improve public health practice for preparedness. It was a very well received meeting, and COTPER is moving forward with some of those ideas for a second meeting that will be held in FY 2010.

In FY 2009, COTPER was very fortunate to receive increased funding for the program. With those dollars, COTPER intends to award two additional PERRCs for a 4-year program, and continue funding the existing 7 PERRCs. With the addition of the two new PERRCs, efforts will now be expanded to 9 administrative cores and 34 R01 research projects, which will give COTPER a greater presence for this research effort on the West Coast. A second All-Grantee Meeting is planned for September 1-2, 2009.

FY 2010 program plans are to expand COTPER's research presence during the 2010 Public Health Preparedness Summit; convene a follow-up workshop with key preparedness partners and engage the practice community and SMEs on methods for translating research findings; a

develop the program content and format for comprehensive research center evaluation during Year 03 of funding (e.g., 2011), in which we hope to engage the BSC. For the summit, COTPER has put forth two NACCHO leadership-specific activities through which research in this program can be highlighted, and others can be brought together who may be engaged in research for preparedness.

Additional preparedness research in COTPER's portfolio includes the following:

- ❑ Improving Public Health Practice through Translation Research (R18)
 - Assessing the Impact of Federal and State Law on Public Health Preparedness University of Michigan; 2-year grant ending September 29, 2009
 - Potential funding for 2 new awards in FY 2009
- ❑ Small Business Innovation Research (SBIR)
 - Three Phase I Research Contracts in FY 2008
 - Cost-effective methodologies to monitor temperature and environmental conditions in forward placed assets
 - Potential funding for 2 Phase I grants in FY 2009

The University of Michigan grant has ended and it is anticipated that the grantee will present the research findings to COTPER and a CDC audience during the second quarter. There is a potential for COTPER to receive two new awards in this same research translation area in the coming fiscal year. SBIR represents another area that COTPER would like to present to the BSC. COTPER has modest dollars for SBIR funding, so it is imperative to make the most of that funding to address specific gaps and research for preparedness and response.

Discussion Points

Regarding real-time data collection, a BSC member inquired as to whether any of the PERRCs were planning to collect data during an actual emergency versus just conducting retrospective reviews of what happened.

Dr. Williams-Johnson responded that all of the research is not retrospective. Some of it is as they move forward through an event. For some projects, some research centers were able to collect real-time data, specifically during the H1N1 outbreak. COTPER will have an opportunity to hear about that research during the All-Grantee meeting in September. In addition to that, the Office of Science and Public Health Practice (OSPHP) is working with the Office of the Chief Science Officer at CDC to develop a format and a formula to conduct real-time research at CDC, and to be able to support that effort in the course of an event. There is a lot of work underway already to be able to capture that kind of data. Some of the grantees were able to make use of funding in their administrative core to engage in that quick, on the ground research. The total amount for each of these pilot projects was approximately \$30,000. There are three examples.

A BSC member reported that Glen Mays has been involved in another project more recently through the Robert Wood Johnson (RWJ) Foundation called The Practice Based Research Networks. The networks are supposed to conduct a project during a two year period. The local health departments or public health institutes are supposed to define the research issue rather than the academic partners. The academic partners help them to make it real through implementation. It was suggested that COTPER talk to Glen Mays or RWJ about expanding the

list from the other side by adding in the practice-based research project defined by the agencies.

Dr. Williams-Johnson responded that the reason COTPER wanted to have a greater presence at the Public Health Preparedness Summit was to foster that kind of dialogue. The research that COTPER has funded was investigator-initiated, and many of these investigators had already engaged their preparedness partners (e.g., local health departments) in framing their research questions. Glen Mays is a co-investigator with the University of North Carolina's Preparedness Research Center. One of their projects is engaging their local health departments in North Carolina on the benefits, strengths, and gaps for the Health Alert Network (HAN).

A BSC member applauded COTPER's efforts to assess applicability because sometimes that is where the paucity is. There is a new funding announcement coming out of what was previously a CPHP program. This member wondered how that effort would affect or interact with COTPER's efforts.

Dr. Williams-Johnson responded that they are not really different funds. They are the same funds in that PAHPA calls for the CPHP. Within those centers, there are specific activities that are called out. Some of those activities will be captured in the new announcement. Research is one of the activities addressed by this particular program that is called for in PAHPA, but the nature of research is that it cannot be blended with some of the other activities. It has to be standalone. All of these activities come under the CPHP as defined by PAHPA.

Dr. Sosin added that the work they heard about earlier pertaining to competencies, curriculum, and excellence in training and education for the preparedness work force would be the focus of the new centers. A smaller number have some of the same mission responsibilities as the original CPHPs, but COTPER will have a larger budget and more oomph behind them to address those issues and the implementation of curriculum.

Dr. Ellis clarified that schools were not precluded from having both a research and a learning center.

A BSC member requested clarity regarding whether the funding is coming from for the R01s, and wondered whether any thought had been given to creating a network so that multi-centered studies could be conducted for some of the larger research questions.

Dr. Williams-Johnson responded that the funding for the program was for the CPHP as identified by PAHPA. These are R01-like rather than R01s per se. Regarding the multi-center question, they are standalone centers in line with the legislation, but COTPER is trying to foster cross-center work and collaboration. Some activities are surfacing in which centers are working together. In terms of a national focus, that is at the program level.

Dr. Sosin added that COTPER has discussed the possibility of new funds going into a broader connected R01 research type of program. There are pros and cons of that, but the first strategy was to begin with the center program and to consider expansion from there as these centers begin to have successes.

A BSC member wondered how the National Center for Public Health Preparedness fit.

Dr. Sosin responded that the piece they focused on was the medical preparedness aspect as opposed to the public health preparedness work in particular—the workforce issues and the medical preparedness curriculum work force type of work. That said, the work that Dr. Young referred to earlier has those components coming together.

Public Health Emergency Preparedness (PHEP) Cooperative Agreement

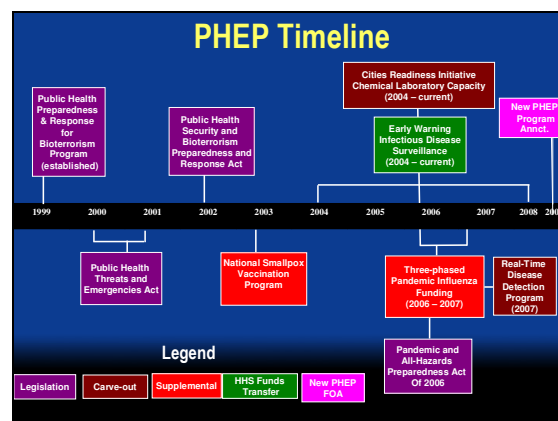
Christine Kosmos, R.N., B.S.N., M.S.

Director, Division of State and Local Readiness

Coordinating Office for Terrorism Preparedness and Emergency Response

Dr. Kosmos indicated that DSLR is designed and supposed to enhance the work of state and locals, and enhance emergency preparedness at the state and local levels. This is accomplished in a number of ways. DSLR administers the Public Health Emergency Preparedness Cooperative (PHEP) Agreement, including funding, technical assistance, tracking progress, and evaluating performance. Technical assistance is an area in which DSLR believes they have a lot of room for growth, and is working hard to develop a more comprehensive technical assistance program within DSLR. In addition to that, DSLR has done some outstanding work in track progress and evaluating performance at the state and local levels. That is a relatively new area for public health preparedness. PHEP basically supports all-hazards preparedness in state, local, tribal, and territorial public health departments across the country.

The 2009 DSLR budget was just under \$700 million, almost all of which is dispersed to state and local health departments through cooperative agreement mechanisms. DSLR has 66 cooperative agreements totaling \$680 million, and funds 62 state and local public health departments and 4 of partner agencies. DSLR has 56 approved positions, 14 of which are vacant, for a 23% vacancy rate. There are 10 unfunded positions, and 21 contractors. DSLR consists of the Office of the Director (OD) that funds some of the positions that supports DSLR; the Outcome Monitoring and Evaluation Branch (OMEB), which engages in a lot of the work regarding performance measurement and evaluation; and the Program Services Branch (PSB), which consists of the Project Officers. DSLR and the PHEP fund 23 Career Epidemiology Field Officers (CEFOs) who are placed in the states. The PHEP timeline is shown in the following figure:



While not in its infancy, Dr. Kosmos quipped that DSLR was probably in its toddler years and as anyone who has raised a toddler knows, these are chaotic times. The PHEP has gone through many transitions throughout the years. There have been several carve-outs, which has resulted in a reduction in the base funds. There have been many quick and nimble changes of the PHEP in order to address the issues of the day and to attempt to provide state and local health departments with the funding they need to do their jobs.

Over the past 10 years, PHEP has shifted from a \$40 million competitive grant to a \$700 million formula-based cooperative agreement. While 53 applicants competed for these funds in 1999, there are now 62 awardees. This is a non-competitive cooperative agreement. It was previously administered in a different division, but is currently administered by COTPER. DSLR works closely with the SMEs who inform the guidance and technical assistance that are within CDC, but outside of COTPER. Originally, it was very bioterrorism-focused with specific focus areas, much of which lingers today in that people refer to it as the "BT grant." Now it has a more all-hazards focus and priority projects in lieu of focus areas. In 1999, CDC was the lead agency for developing capabilities, while there is now significant input into the development of the guidance from CDC's federal partners.

Several years ago, there was an urgency to develop benchmarks and methods for evaluating the impact of the funding at the state and local levels. Some of the efforts that DSLR has been able to evaluate and that have resulted from preparedness funding are that, of the awardees, 100% have response plans for at least one priority agent, 100% have exercised response plans in the last 12 months, 100% have established Incident Command System structures, and 100% evaluate urgent disease reports 24/7/365.

As of a month ago, DSLR administered and provided technical assistance around the PHEP grant, but has now moved into a new era with the Public Health Emergency Response (PHER) grant. This is the grant that was developed to fund state and local health departments for H1N1 accelerated planning and response. It was established in 2009 by the Supplemental Appropriations Act and is designed to fund state and locals for public health departments to prepare and plan for H1N1 in two focus areas: 1) Mass Vaccination, Antiviral Distribution, Community Mitigation; and 2) Epidemiology, Surveillance, and Laboratory.

Funding to date is broken into three phases. Phase I and phase II are very similar. Phase I includes the two focus areas, with funds in the amount of \$260 million, which have already been awarded to the state and local levels. This was awarded based on the population formula because that was what could be done at the time. Phase II in the amount of \$248 million does not have new deliverables. It is meant to accelerate the planning of the first focus area (e.g., mass vaccination, antiviral distribution, and community mitigation). Phase III remains to be determined. This is a half a billion dollars, but more money is coming down that will fund the implementation of a mass vaccination campaign. DSLR is busy writing that guidance. Basically, they have compressed three years of work into weekends and holidays over a month to six weeks.

With regard to challenges, there is a need to develop a structure within DSLR that is prepared and able to enhance state and local preparedness in terms of the technical assistance. There must be a more nimble structure for doing this. In addition, issues need to be identified in a proactive manner. SMEs must be able to be brought in to help state and local health departments with the long-standing and urgent needs. In addition to that, structure must be built within DSLR, drawing upon the expertise of others, to translate preparedness science into practice. Otherwise, they will have 62 awardees trying to solve all of their problems in their own

cocoon. Fiscal oversight must also be assured, which is a major responsibility. DSLR is under a lot of pressure to disperse funds, do that well, and to assure accountability. They must do a better job of providing good technical assistance on the front end pertaining to fiscal oversight. Awardees must also be assisted in advancing preparedness through access to funding and coordinated, proactive technical assistance.

Discussion Points

Dr. Sosin noted that Dr. Kosmos was a new key staff member, which was the result of an extensive search, outreach, and recruitment process. One of the ways hospital preparedness links with public health emergency preparedness is through Dr. Kosmos, who ran both programs in Chicago. Another way for COTPER to improve visibility, awareness, and engagement at the state and local levels is by bringing quality people into the organization who have worked at those levels. He stressed what a fabulous job she had done to date, particularly having come on board in the midst of H1N1, et cetera.

One BSC member commented that there were some interesting opportunities to link Challenges 2 and 4 in order to “connect the dots.”

Dr. Kosmos responded that translating preparedness science into practice is something that Drs. Sosin, Williams-Johnson and others within COTPER can really help with. They would like to develop a unit within DSLR of groups that can translate the information from the state and local levels and from the research that has been conducted into practice. For example, for the H1N1 response, they developed a comprehensive gap assessment tool that is designed to help states and locals identify what they need to be ready and able during the fall for a mass vaccination campaign. This goes beyond process measures and delves into the capabilities that will be required. Those gap assessments are due back to CDC at the end of August, at which time CDC will evaluate that data and put a team of experts together who can assess the data in terms of what it mean about the country and individual jurisdictions. Based on those data, real interventions will be implemented at the state, local, regional, and national levels. This is a good illustration of turning science into practice.

A BSC member requested information about the process for disseminating funds to state and local levels, and whether poor applications were funded.

Dr. Kosmos responded that while it is not a competitive application, they do have to apply. The emergency preparedness grant is more for planning. The process associated with that involves SMEs designing a guidance document, helping to write that guidance, and then publishing it. The PHER is a different process because the thrust of that was to get funding out without a very good application process. There was an expedited application process because they wanted to get money into the system quickly so that funds could go from states to the local level. The deliverables are submitted later when states and locals have more time to assess their gaps and develop work plans to address them. Regarding poor applications, there is some tension because some awardees are so small they do not have the infrastructure to spend. There are mechanisms to restrict funding until a more complete or better application is received.

Dr. Sosin added that Dr. Kosmos was being very careful because there are legal implications. For the most part, all applications are funded unless they are missing something. When the gaps are identified, these become the focal point of the project officers making sure that the support is provided. COTPER is using the weaknesses of those applications as driving the support that those groups are going to need.

A BSC member asked for clarity regarding public health's role in resiliency, absorbing the impact, and rebounding or recovering from it. That is, starting with the assumption that there will be no recovery unless the population is mentally and physically healthy. Then public health is a major part of it.

Dr. Sosin responded that COTPER is highly focused on the detection and initial response side. There are many activities in public health that relate to mental health, which has a major impact on resilience (e.g., emergency communications, giving people useful actions to take, minimizing tension and stress involved in emergencies, et cetera). There are many areas in which public health plays a role in resilience leading up to an actual event, and in recovery. To be fair, COTPER has not laid out the back end in the same way as they have worked through scenario-based operations and response plans assuming that they will figure it out when they get there. While this is not the best solution, it is one that balances the wide range of demands and needs.

Dr. Kosmos added that the draft of the National Health Security Strategy focuses on mentally and physically healthy populations, so that issue is likely to move more to the forefront.

Dr. Sosin introduced the new Vulnerable Population's Officer, Dr. Mark Bashor. The point regarding a public that is healthy and therefore more resilient is a major focus of preparing vulnerable populations as well. It is a small token of investment and input that COTPER expects to grow.

A BSC member pointed out that in a society where so much of the medical care that people see is in the private sector, but where the only obvious convener and coordinator is governmental public health, it can appear like a complete disconnect to funders, particularly Congress. Having language that helps to explain the system, where their money is going, and what it is doing is going to be incredibly important over the long-term.

A liaison member commended DSLR for their timely influenza response. Regarding the fifth challenge, capture and development of a process that serves as a model to deal with the 23% vacancies should be added. This is an opportune time, given that there has never been an incident such as this in which there has been such a massive vaccination campaign.

Biosurveillance Coordination Unit (BCU)

Curtis Weaver

Biosurveillance Coordination Unit

Office of Science and Public Health Practice

Coordinating Office for Terrorism Preparedness and Emergency Response

Mr. Weaver explained that the Biosurveillance Coordination Unit (BCU) is a newly formed unit within COTPER, which was the result of Homeland Security Presidential Directive 21 (HSPD-21). The BCU was formed to coordinate interagency efforts related to HSPD-21. Its mission is to coordinate the development of a strategy and operational plan for integrated, nationwide public health surveillance to safeguard people from acute events by building upon current capabilities that strengthen local public health practice and provide value to medical care.

"Biosurveillance" is a relatively new term found in HSPD-21, which can often be confusing because it is more than just biological threats and more than just public health surveillance. The definition of "biosurveillance" in HSPD-21 is, "*active data-gathering with appropriate analysis*

and interpretation of biosphere data that might relate to disease activity and threats to human or animal health --whether infectious, toxic, metabolic, or otherwise, and regardless of intentional or natural origin--in order to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity" [HSPD-21, paragraph 2a]. This is an all-hazards type of approach to provide early warning and ongoing situational awareness with the back drop of a public health emergency.

From a public health perspective, biosurveillance is "the science and practice of managing health-related data and information so that effective action can be taken to mitigate adverse health effects from urgent threats." Information is a supply chain: What decisions have to be made during a public health emergency? What information is needed to make those decisions? How fast is the information needed? What specific parts of the information are needed? What systems supply that information? How can it be harnessed together into one picture in order to make informed decisions? How can the information be shared vertically and horizontally during an event so that others understand the same picture and can make informed decisions as well?

The concept of enhancing this capability is not new. It began in 2004 from a federal perspective with HSPD-9 and 10 which called for the creation of a new biological threat awareness capacity, and the establishment of an integrated warning system. This continued with the 2006 Pandemic and All-Hazards Preparedness Act (PAHPA) legislation, and the 2007 HSPD-21, which mandates the need to "*establish an operational national...[bio]surveillance system for human health*" and "*Federal Advisory Committee ... to ensure that the Federal Government is meeting the goal of enabling State and local government public health surveillance capabilities.*"

Early on, the BCU established partner workgroups comprised of federal agencies with a role in biosurveillance. A state, local, territorial, and tribal workgroup was also established. In addition, there is a workgroup of SMEs from across CDC with whom BCU meets periodically for assistance in developing the strategy. They also have a forum in which to meet with senior CDC leadership on a regular basis to share ideas, build consensus, and obtain guidance on the direction of the unit. Through that effort, they have come to realize what enhanced capability should look like, which includes the following:

- ☐ All-source, relevant, accurate, timely, and actionable information for government, healthcare, business, and personal decision-making around health emergencies
- ☐ Improved horizontal and vertical information sharing
- ☐ Enhanced capability through shared responsibility
- ☐ Related initiatives integrated and priorities set collaboratively for limited resources

Also required is a workforce with new skills and greater capacity; new science that bridges information and analytic fields, includes data and information safeguards, and engages in responsible application of new methods; and modified workflows and business processes. Yet, there remain a number of challenges. There are workforce limitations in that there have been capacity reductions at the most skilled end of the workforce. Moreover, there is a lack of competencies, curriculum, and mechanisms to prepare and train the biosurveillance workforce of the future. There is a considerable amount of duplication of efforts; however, there is constrained data sharing, and limited interagency collaboration and visibility of relevant work. Unstable funding contributes to the challenges in that it impedes research and development, recruitment, retention, and collaboration.

In order to address enhancing capacity, the BCU has been working on three activities or products over the past several months: 1) The National Biosurveillance Strategy for Human

Health (NBSHH), 2) the Concept Plan for Implementation of the NBSHH, and 3) the National Biosurveillance Advisory Subcommittee.

The NBSHH strategy builds on current capabilities and relationships; respects multi-organizational and multi-disciplinary perspectives; ensures protection of rights and authorities; and serves as a reference point for the next generation biosurveillance capability. Version 1.0 was distributed on December 15, 2008 and Version 2.0 will be distributed in November 2009.

This is a major and complex problem. With the assistance of the stakeholder groups, the following priority areas were settled upon:

- ☐ Electronic Health Information Exchange
- ☐ Electronic Laboratory Information Exchange
- ☐ Unstructured Data
- ☐ Integrated Biosurveillance Information
- ☐ Global Disease Detection and Collaboration
- ☐ Biosurveillance Workforce of the Future

Within the strategy, there are broad goals and objectives for each of these priority areas and an explanation of what these priority areas are. School closures during H1N1 illustrates reaching outside of normal public health surveillance systems to garner information about what is occurring with the human health of the US during an event. Integrated biosurveillance information tells the story of what is occurring, and can be communicated to others horizontally and vertically such that everyone understands the same picture.

The Concept Plan encourages interagency collaboration and more effective data sharing. Two of its main components are the National Biosurveillance Registry for Human Health and a Governance Model to formalize collaboration. The draft version of the Concept Plan was distributed to stakeholders on July 20, 2009. HSPD-21 also called for a National Biosurveillance Advisory Subcommittee (NBAS) to be formed *“to ensure that the Federal Government is meeting the goal of enabling state and local government public health surveillance capabilities.”* NBAS was established on May 1, 2008 to provide council to the Advisory Committee to the Director of CDC to: 1) review, research, and guide the National Biosurveillance Strategy for Human Health on an annual basis; and 2) serve as an innovative engine for advancing nationwide biosurveillance capability. It consists of 30 prominent public and private biosurveillance stakeholders and contributors to ensure independent input. When NBAS formed, they organized themselves into 8 task forces and 8 focus areas. They went through a process in which they developed reports on recommendations, some granular, some very specific action steps within each one of those 8 task force areas. That was then boiled down to 5 recommendations that are now prepared for the ACD to review at the first of September 2009.

Next steps with regard to the Concept Plan are to incorporate feedback into the draft version of the Concept Plan and prepare for external distribution; and utilize the Concept Plan to foster additional collaborative relationships across all levels of government. With regard to NBSHH, the current version of the strategy will be revised to reflect the direction necessary for enhanced biosurveillance. The strategy will broaden the scope of biosurveillance through additional input from various stakeholders. ACD approval of the NBAS final report is anticipated during the September 2009 meeting.

Discussion Points

An *ex officio* member pointed out that what Mr. Weaver presented appeared to be primarily focused domestically.

Mr. Weaver responded that one of the priority areas is global, and there are some global aspects in the final recommendations from the NBAS.

Dr. Sosin pointed out that the HSPD itself is about domestic preparedness and response to protect the US. This cannot be done without visibility of what is going on internationally. Not just visibility, but building capacity internationally to have early warning, early detection, and situational awareness. This activity is not a new focal point to build a new system or to create a mega network system that is run by this activity; it is really about strategy and implementation governance. This center will not conduct data analyses or consolidate data from all of the open source systems. The intent is to ensure that there is an effort to gain a broader, more efficient, and more effective application of this system of biosurveillance.

It was noted that one of the Global Health Security Initiative projects is examining various open source systems in an effort to get them to work together to validate the information, and be able to more rapidly detect whether there has been an intentional chemical, biological, radiological and nuclear (CBRN) event.

Mr. Weaver indicated that during the H1N1 response, the BCU did not have a desk or perform any operational tasks, but infused themselves into different components of the response. Afterward, they had an opportunity to help conduct a review to assess the information supply chain to answer questions such as: What decisions were made? What information did you need?

A liaison member pointed out that while it was important to coordinate with Homeland Security, it is not a health agency. It seemed that the good and bad news reflected in Mr. Weaver's report was that Dr. Frieden supports surveillance and epidemiological response. This is good news because this is within his area of expertise. It is bad news because it is not clear how this relates to what all public health people have been doing for years. For example, it is not clear where or how Council of State and Territorial Epidemiologists (CSTE) is involved in this. How can someone distinguish an urgent threat from an endemic threat? Cigarette smoking, trans fats, obesity, multi-drug resistant tuberculosis, methicillin-resistant *Staphylococcus aureus* (MRSA), et cetera, are monitored in surveillance system embedded within state health departments, hospital infection control systems, and CDC. These are not urgent threats in same sense than an anthrax outbreak would be, which will be interpreted with either diffidence or lack of experience by Homeland Security. Perhaps that was not the intention of the President's Directive in 2007, but is right in the wheelhouse of all state and local health departments. The term "biosurveillance" can be defined to be only urgent threats, although it is probably not defined that way by Dr. Frieden who would define it in a much broader way. Thus, it would seem that one of the challenges regarded how to bring this back into state, local, and national public health surveillance of health-related conditions. It was not clear how this related to the Coordinating Center or its various components, or the surveillance functions throughout all of CDC's categorical programs.

Dr. Sosin responded that they would be happy to make this the topic of a broader discussion at a future meeting. He clarified that the Homeland Security Presidential Directive was Homeland Security-based, but it directed the Secretary of Health and Human Services (HHS) to do this work in coordination with the other relevant departmental secretaries and really was talking about human health. This particular Presidential Directive said this is the core of the entire broader spectrum of biosurveillance. It is a focus on the urgent threats. MRSA might be classified as an urgent threat, although obesity probably would not. Information flows needed on a daily basis changes enough, so it is important to have visibility in that kind of timeframe to move, adjust, change programs, and potentially respond differently. Acknowledging that this is not all that Dr. Frieden wants to address, it is a critical piece. The Presidential Directive speaks significantly to building on the capabilities of state and local public health. It is a Homeland Security priority, but it is about public health infrastructure and public health functions that need to be strengthened to make more flexible, more adaptable, and more responsive public health systems. It is not everything needed for surveillance and epidemiology, but it is a critical piece that focuses significantly on the timeliness of moving data, interpretation of data, fusion of information, management of information, and distributing information effectively.

A BSC member pointed out that there remain a number of problems in anti-terrorism with respect to how surveillance is perceived in terms of public, particularly with respect to ruling organisms in or out rapidly and effectively to detect something early before there are dozens of people in emergency departments. After 11 years, state public health systems are being told that they cannot utilize bioterrorism funds to work on normal organisms; however, it is not possible to know whether an organism is normal unless it is identified. It follows from that that there is still a severe need to examine capacity for radiation and chemical detection. Those have to be put back into the equation as well, on the front end, rather than waiting until there is a crisis.

Dr. Sosin replied that there is now more of an opportunity to build that case about how this should support the everyday issues in order to better understand the unusual ones.

A BSC member thought that perhaps the biosurveillance model and some of the data being collected might also be related to the overall process a crisis from the original crisis audit through planning, mitigation, response, and recovery. That is, it may help to better interpret the biosurveillance data by tying it to the stage in the crisis at which the data become critical for mitigating the next stage.

Mr. Weaver referred members to a fact sheet included in their materials that defined biosurveillance and mentions that it is active throughout the entire cycle.

Public Comment – Day 1

No public comments were offered during the first day of the meeting.

FRIDAY, AUGUST 14, 2009**Call to Order / Welcoming Remarks – Day 2**

Barbara Ellis, Ph.D.
COTPER Designated Federal Official
Deputy Associate Director for Science
Coordinating Office for Terrorism Preparedness and Emergency Response

Dr. Ellis welcomed everyone back to the second and last day of the August 2009 BSC meeting. She reminded everyone that they had considerable flexibility with regard to the mechanisms they could use for external peer review of COTPER'S programs, such as Institute of Medicine (IOM) studies or ad hoc panel reviews. COTPER's primary and preferable means of conducting reviews is using BSC ad hoc workgroups, which consist of at least two BSC members co-chairing a workgroup. Regardless of the mechanism used, the results from the external program review are reported to the full BSC for deliberation and a vote on any recommendations that are made as a result of the review. After the external review is reported to the BSC, COTPER's programs will provide a formal response with respect to the recommendations that have been approved.

The previous day, the BSC heard from Dr. Lindsey with respect to a formal response to the BSC's recommendations that were made following the Fiscal Allocation Process peer review. During the second day, they were to hear from Jerry Diaz from the Homeland Security Studies and Analysis Institute (HSSal), formerly the Homeland Security Institute (HSI), regarding the observations and recommendations that were made from an external peer review of the Division of Select Agents and Toxins' (DSAT) Select Agent Program. COTPER selected this organization because it is a Federally Funded Research and Development Center (FFRDC). The impetus for this study was the result of a commitment that Dr. Besser made at a Congressional hearing of the House Committee on Energy and Commerce in October 2007 to conduct an external review of CDC's Select Agent Program (SAP). The contract for this review was put into place prior to the establishment of the BSC. Due to administrative challenges, the original scope of the review had to be significantly reduced. Dr. Diaz and his reviewers spent three weeks with the division staff, so while there was a reduction in scope, considerable effort was still put into the review. Dr. Weyant and his colleagues had an opportunity to provide comments regarding technical inaccuracies and ambiguities of the report on an earlier draft.

During this BSC meeting, Dr. Ellis indicated that Dr. Diaz would present on the observations and recommendations made by the reviewers. Two of the reviewers were also present during this BSC meeting to answer any technical questions posed concerning the report: Dr. Reynolds Salerno, an internationally recognized biosecurity expert from Sandia National Laboratories; and Dr. Henry Mathews, an internationally known biosafety expert. In addition, she indicated that Dr. Rob Weyant would provide perspectives from the program regarding the report. Dr. Ellis stressed that everyone understood that these would not represent a formal program response to the recommendations in the report, because the BSC has not yet deliberated and voted to approve the recommendations. She assured everyone that subsequent to hearing Dr. Diaz's presentation, the board would have an opportunity to ask questions, deliberate on observations, and vote on the 29 recommendations contained in the report.

DSAT External Peer Review by HSI / Technical Comments / Discussion / Vote**Division of Select Agents and Toxins External Peer Review by the Homeland Security Institute (HSI)****Gerald Diaz, Ph.D., HSSal****Henry Mathews, Ph.D., Biosafety Consultant****Reynolds Salerno, Ph.D., Sandia National Labs**

Dr. Diaz expressed gratitude for the invitation to address the BSC. Homeland Security Institute (HSI) considered it an honor not only to present to the BSC, but also to have been selected to conduct this review for COTPER for DSAT. He introduced HSI's two SMEs who were in attendance, Drs. Matthews and Salerno. Dr. Matthews spent 24 years at CDC, where his last job was as the Safety Manager responsible for all biosafety programs within CDC's Infectious Disease Labs. Dr. Salerno is currently the manager of the International Biological Threat Reduction Global Securities Program at Sandia National Labs, and has spent the last 5 years with his team consulting in over 25 different countries in the area of biosafety and biosecurity issues.

HSI is not-for-profit FFRDC, and are contractors not government employees. Similar to the labs, HSI's relationship with the government tends to be unique in that they are permitted to review budget information (unless it pertains to HSI's budget) and attend closed-door sessions. HSI was established to help the government, particularly DHS, make the types of decisions that a for-profit contractor would not be permitted to make. Every Secretary is allowed to have his or her own FFRDC. This FFRDC is now known as the Homeland Security Studies and Analysis Institute (HSSal). DHS has two FFRDCs, the HSSal that focuses on studies and analyses, and another that focuses on systems engineering. The HSSal FFRDC is to produce scientifically rigorous, empirically-based, fully coordinated research that provides actionable recommendations.

COTPER was the sponsor of this study about which Dr. Diaz was reporting. COTPER approached HSI to request that they review DSAT's internal processes. In many ways, this was a classic business improvement challenge. Any organization that goes through a tremendous growth spurt as DSAT has experiences significant organizational challenges. DSAT increased from approximately 12 to approximately 80 staff members within 5 years. In that sense, it was not unique to the challenges other organizations face. What made it unique was the importance of the DSAT program and the technical aspects that needed to be carried forward. The focus of the HSI DSAT study pertained to the registration of regulated entities, response to requests for select agent transfers, DSAT recordkeeping and information technology practices, Enforcing entities' compliance, inspections of entities, training of DSAT personnel (government and contractors), and DSAT's self-evaluation activities.

HSI examined certain internal DSAT processes for completeness and efficiency, to identify strengths and weaknesses, and to develop suggestions for improvement. In March and April 2009, HSI conducted non-attributational interviews of key DSAT staff, reviewed DSAT policies, procedures, and records, anonymously surveyed DSAT inspectors, accompanied DSAT inspection teams on entity inspections, and analyzed observations and gathered information.

HSI's Independent Review Teams included a diverse group of external SMEs with varied expertise, including biosecurity, biosafety, disaster preparedness, facility security, infectious disease, information technology and informatics, inspections and regulatory compliance, process improvement, public health, risk management, and veterinary health. These SMEs worked side-by-side with HSI analysts on every step of the DSAT program review. HSI assembled SMEs' inputs and conclusions, but did not seek to drive them toward a consensus.

The key findings of the DSAT program review were grouped under seven broad headings: Mission and Strategic Plan, Records Management, Process Documentation, Inspections, Training and Self-Evaluation, Staffing, and Guidance and Outreach.

With respect to the mission and strategic plan, HSI found that there is ambiguity in DSAT's mission, notably regarding DSAT responsibility for oversight at unregistered entities. The DSAT mission, in general, is to ensure safe and secure possession, use, transfer, and storage of select agents and toxins. This is a very broad mission statement and can be carried out only those entities that are registered. If illegal laboratories are engaged in practices they should not be, it is not possible for DSAT to ensure safe, secure possession, use, and transfer of these agents and toxins. The SMEs on the review team realized that this is likely not DSAT's responsibility; however, it flagged as an issue in the event that there was an incident in the future that called into question why DSAT did not take responsibility. HSI also believed that DSAT should develop a strategic plan to play a critical role in designing and implementing all other organizational changes, set its overall direction, prioritize and sequence improvements while managing temporary disruptions, and create timelines and accountability for change. To address these issues, HSI recommended that DSAT:

- ☐ Clarify, explicitly state, and widely promulgate DSAT's mission; and
- ☐ Develop and implement a strategic plan to be led by the Operations Director (a currently vacant position), ensuring the commitment and participation of high-level leadership; limit specific leaders' ongoing responsibilities so that they can focus on long-term evolution of the organization. This process is underway.

In terms of the records management findings, DSAT's reliance on both paper records and the National Select Agent Registry (NSAR) database prevents critical needs from being met. In a survey conducted by HIS, inspectors reported being very frustrated with the overall recordkeeping process, especially the NSAR database. Although the NSAR database has an ability to conduct data searches, it is somewhat limited in being able to conduct trends analysis, cross-referencing, and queries. Some of these in depth data searches need to be done by hand. There is an increasing amount of paperwork that is growing at a very high rate, which means that the more in-depth the data search needed, the more intense the manual labor required. Current records management processes generate excessive paper files (many tons annually), limit DSAT's ability to respond to time-sensitive data requests, cannot interact with standard software packages, require manual re-entry of information multiple times, require hundreds of pages of paperwork per form by entities, and require manual cross-checking for inconsistencies. Nevertheless, HSI observed a high degree of attention to detail, care, and diligence by everyone involved in the records program. To address these issues, HSI recommended the following:

- ☐ Identify the resources needed to recruit rapidly SMEs to research and contrast available solutions;

- ❑ Implement and integrate an enterprise-wide solution superseding the paper-based problems and the NSAR database;
- ❑ Create a design document that describes the needed functions of the system and clearly sets system requirements. Clearly, the NSAR is following some sort of requirements. DSAT needs to talk to users to define what their real needs are. This is the voice of business. A comparative analysis should be conducted of what is commercially available. There are certainly commercial products available, such as Oracle, that could be used to build a front end that would do all of this. There may be ways to turbo charge NSAR with some sort of commercially-based products;
- ❑ Ensure that any system that supplants NSAR meets the following minimum requirements:
 - Compatibility with software programs commonly used by DSAT, such as Microsoft Word, and Microsoft Excel
 - Compatibility with all Animal and Plant Health Inspection Service (APHIS) / CDC Forms (existing and revised)
 - Capable of executing rapid queries
 - Capable of incorporating compliance information
 - Remotely accessible to inspectors
- ❑ Obtain input from the regulated community regarding any proposed changes to the system.

Pertaining to process documentation, DSAT needs to more thoroughly document and give official status to its procedures. Many standard operating procedures (SOPs) and process flowcharts remain in draft form for years because of the coordination required by multiple agencies to review and approve them. As such, DSAT has taken the necessary initial steps in developing draft SOPs for its staff and the regulated community. To address this issue, HSI recommended the following:

- ❑ DSAT should create, validate, and disseminate SOPs and flowcharts to govern the following processes:
 - DSAT inspector training and qualification
 - Processing of transfer requests
 - DSAT inspections of entities
 - Facility risk assessments by entities
 - Rigorous review Entities' biosafety and biosecurity risk assessments by DSAT inspectors
 - Determining the composition of inspection team
 - Explaining DSAT's oversight risk assessment procedures and effective determination for registration duration and non-routine inspections for entities
 - Process for determining a "cease and desist" order at entities
 - Conduct of inspections
 - Duties and responsibilities of Responsible Officials (ROs) and Alternate Responsible Officials (AROs)
- ❑ Appoint a senior leader with ownership responsibility for overseeing completion of SOPs and flowcharts;

- ☐ Revise its SOPs to correspond with DSAT's mission statement, specifically with regard to whether DSAT intends regulatory authority over non-registered entities and persons;
- ☐ Develop a timeline for creating new SOPs and giving official status to its draft SOPs; and
- ☐ Include creation of new SOPs (as listed) and giving official status to draft SOPs as a priority in an overall DSAT strategic plan.

Concerning inspections, DSAT inspections largely focus on biosafety issues at the expense of biosecurity issues. Inspectors generally have some background in biosafety having largely worked in biosciences previously, but no prior experience in biosecurity. Biosecurity is not addressed in DSAT's current formal training. There is also a lack of standardization in conducting and scheduling inspections. SOPs have not been formalized and promulgated. Inspectors indicated that they were not trained specifically and formally regarding how to conduct an inspection. There is a lack of clearly defined frequency between inspections. It is not clear whether DSAT inspectors have been comprehensively trained in risk assessment, or made capable of critically evaluating the quality of an entity's risk assessment. The inspectors who were surveyed stated that they felt more training in biosafety was necessary, and they also desired training in additional areas such as biosecurity, facility engineering, and incident response planning. DSAT inspectors do not currently evaluate the degree to which operational biosafety and biosecurity protocols reduce the risks identified in risk assessment. The majority of the items on the inspection checklists are drawn from the Biosafety in Microbiological and Medical Labs (BMBL) and do so without regard for prioritization. While the BMBL is good, its emphasis is on biosafety. To address these issues, HSI recommended the following:

- ☐ Conduct a risk assessment and prioritization of inspector checklists. Ensure that technical topics (risk assessments, plans, and training for both biosafety and biosecurity) are the highest priority for DSAT. Ensure that checklists are clear and precise, with limited variability in interpretation by the inspection team. Explore a process for weighting checklist findings for severity, based on the entities' characteristics;
- ☐ Develop SOPs, processes, and guidance. Develop formal guidelines, including an SOP, that outlines what authority a lead inspector has in dealing with potentially dangerous situations in the field. Develop DSAT oversight risk assessment policies and guidance that includes a program to prioritize entities for establishing different periodicity for registration renewal. Develop a formal process for staffing inspection teams to take advantage of unique skills each member possesses. Accelerate and standardize the internal "risk assessment" process significantly to prioritize inspection frequencies and focus areas among the 342 registered entities. Develop templates and examples of risk-based plans for the regulated community;
- ☐ Elevate the importance of laboratory biosecurity within DSAT to the level of biosafety by defining the core competencies related to biosecurity inspections; ensuring that all inspectors are trained to these levels by establishing metrics to evaluate learning; pursuing external training on biosecurity risk assessments; and developing methods to evaluate the effectiveness of an entity's biosecurity risk assessment and effectiveness of the overall lab's biosecurity system.

Given the time constraints, Dr. Diaz completed his presentation by discussing only the recommendations for the remaining topics rather than presenting the findings, followed by the recommendations.

With regarding to training and self-evaluation, HSI made the following recommendations:

- ☐ Develop a formal training program to define the critical skill and knowledge levels that need to be addressed. This program should include training in select agent compliance, biorisk management perspectives, and risk assessment. This program should use a performance outcome-based approach;
- ☐ Develop training metrics and documentation processes. DSAT should identify the core competencies required of inspectors and train to those competencies, including communication skills;
- ☐ Provide regular access to additional training. Areas to consider for further training include: biosecurity, building automation systems, facility design, primary containment devices, interviewing techniques, risk assessment, and NIH's *Recombinant DNA Guidelines Advanced Training in Specialized Areas for Inspection of Large or Complex Entities*;
- ☐ Adopt the following continuous improvement "best practices" to select and implement its improvement projects:
 - Use measureable output metrics to evaluate the current performance of key processes
 - Prioritize improvement opportunities based upon three factors: the size of the performance gap (i.e., difference between current and required performance), risk if the gap is not closed, estimated effort/resources required to close the gap
 - Select only a few projects at a time to implement and work these projects quickly through to completion
 - Compare the post-implementation level of performance against baseline performance
 - Document the new process
 - Train new and existing personnel
 - Continue to periodically review and measure performance

When an organization grows by a factor of 10, such as DSAT has done it is cause great stress and strain on an organization. What typically occurs is that such organizations grow by evolution. HSI made the following recommendations with respect to staffing:

- ☐ Conduct a comprehensive administrative review of DSAT's staffing needs, staff functions, roles and responsibilities to identify possible efficiencies, improve future program planning, and create means of establishing staff redundancies (e.g., mentoring, succession planning); and
- ☐ In the meantime, ensure that all critical roles have at least two individuals who are trained and designated to fulfill them; increase additional inspector staff to reflect increasing numbers, scope, and intensity of inspections; and cross-train staff.

With respect to guidance and outreach, HSI felt that DSAT was doing an excellent job of outreach to the regulated community and in training for guidance and form completion. With that in mind, HSI recommended the following:

☐ Develop, revise, and promulgate guidance documents for the entities

- Continue developing entities guidance for form completion
- Update this guidance as necessary and post updates to selectagents.gov
- Consider publishing a "Guidebook for ROs," and continue regular updates based on lessons learned; additional guidance from DSAT on its interpretation of regulations and guidelines based on lessons learned and field experience would be very beneficial to the community
- Revise and improve the biosecurity risk assessment guidance that DSAT provides to entities
- Develop and provide guidance on biosecurity drills and exercises for regulated entities

In summary, The HSI Independent Review Team was exceptionally well-received by the DSAT leadership and staff. The team recognized that many of the findings and potential solutions were already identified by the DSAT staff and underway. As with any study, there are a number of opportunities for further review and analysis. DSAT has a terrifically important mission and the team hopes its efforts will assist the division in keeping our nation safe.

Technical Comments from the Program:

Robbin S. Weyant, PhD, Director
Division of Select Agents and Toxins (DSAT)
Coordinating Office for Terrorism Preparedness and Emergency Response

Dr. Weyant thanked the BSC for the opportunity to present an update on the DSAT program, and to provide some additional input on what the program has been doing primarily in conjunction with the issues identified by the HSI. As Dr. Diaz mentioned, many of these issues have been on the DSAT staff members' minds. The DSAT staff appreciated the opportunity to have an external review group help to crystallize their thinking and further develop their way forward. He thought in this case, the government's money was extremely well spent and resulted in some great recommendations from which DSAT could work.

As Dr. Diaz indicated, the DSAT staff had been thinking about a lot of these issues already. In January 2009, the leadership group of DSAT decided to engage in a two-day strategic thinking process. During this time, core operations were assessed and DSAT engaged in an exercise to identify and prioritize its needs. Resources and how they could best be applied were examined, and a series of initiatives and accountability measures associated with those initiatives were established for specific DSAT leaders. Some of the initiatives clearly dovetailed with Dr. Diaz's presentation. Major DSAT initiatives for 2009 in various areas include the following:

☐ Select Agent Inspections:

- Recruit and train at least 6 additional federal select agent inspectors so that additional routine and non-routine inspections can be performed.
- Develop formalized procedures for non-routine inspections (unannounced, 24-hour notice, follow-up on findings, incident investigation, et cetera). Obtain input and concurrence from APHIS.

☐ Select Agent Transfer Oversight

- Complete the current pilot for “white glove” protocols and develop an options paper for CDC management and APHIS.

☐ Emergency Response

- Update DSAT SOPs to ensure that both predictable and unpredictable events are covered.
- Update our MOU with CDC Emergency Operations Center to address the routing of emergency requests.

☐ Policy Issues and Rulemaking

- Recruit a DSAT Associate Director for Science to coordinate intra-governmental Select Agents & Toxins Technical Advisory Committee Activities; other rulemaking, COTPER Science Office initiatives, and DSAT Training Program

☐ National Select Agent Registry (NSAR)

- Integrate APHIS: Originally, CDC and APHIS each set up their own interface programs through separate contractors. However, over the last year and a half, through negotiations with APHIS, and 100% common interface was ultimately achieved.
- Development of a secure portal that can be made available to all of the responsible officials around the country, so that rather than faxing or sending paper-based information to DSAT they can interface with NSAR electronically through a secure web-based portal. One of the main obstacles to that was the two different interfaces, which is now resolved. Significant progress has been made in this area, and DSAT hopes that the secure portal will be set up within the next year to year and a half.
- Improve system efficiency and reliability; this is significantly underway.
- Perform a comprehensive audit of NSAR information. This has not been done since the system was set up.

Several concrete efforts have been made in support of the goals and objectives established in January. Recruiting goals for 2009 included 6 Inspectors (GS-11/12), a Federal Team Lead (GS-13), and Operations Manager (GS-14), and Associate Director for Science (GS-14), and NSAR Support Person (GS-12/13), and a Security Specialist (GS-13). Two inspectors and the Operations Manager and Associate Director for Science have been hired. The recruiting process for the NSAR support person is underway.

With respect to the concerns raised by HSI for unregistered entities, DSAT will review its mission statement and enabling legislation, along with legal counsel, to determine whether the mission statement reflects the wishes of Congress when the program was established in 2002.

Several current efforts are in place to address situational awareness activities: Select Agent Identification Reporting System (CDC/APHIS Form 4), Select Agent Transfer System (CDC/APHIS Form 2), CDC Etiologic Import Permit System, and literature surveillance. The literature surveillance program is a pilot program through which DSAT identifies papers that discuss select agent issues. Upon identification of these papers, DSAT staff examine the authorship and institutions involved in the work described. If it is found that they do not match DSAT's records, outreach is done to determine the involvement of the work and whether they need to register. DSAT has mechanisms in place to address unregistered entities.

Regarding efforts to improve NSAR, DSAT has recently contracted with a third party IT specialty group known as Compass. Compass will examine the architecture of NSAR and provide a specific roadmap for improvements. DSAT recently revised all of its forms, and in conjunction with this the requirement that when entities renew, an internal audit will be conducted to compare the information on the new forms with what is in the paper and electronic databases. Once any discrepancies are resolved, the paper files used for the old forms will be retired. Two scanners have been purchased, so everything that now comes in is scanned and converted to an electronic format. This technology will also be leveraged to move away from the paper working files so that the inspectors can work with electronic files. As noted earlier, integrating APHIS was a significant step in improving the efficiency of the process, as will be the external portal.

The new Operations Chief has a primary responsibility for SOP development and maintenance, and is supervising inspection team leaders so that as SOPs are finalized, they are communicated to the inspection teams in an efficient and organized manner. With its APHIS colleagues, DSAT recently completed a comprehensive SOP for inspections.

DSAT agree with HSI that training is critical. The current training approach includes initial didactic training on the select agent regulations and associated reference documents (*Biosafety in Microbiological and Biomedical Laboratories*, NIH Guidelines, applicable Occupational Safety and Health Administration standards). Following the didactic training period, they engage in an on-the-job apprenticeship. They begin as observers who go on a number of inspections to observe the activities of an inspection team. They subsequently become a junior member on the inspection team, a support person for a senior inspector, and are ultimately given the responsibility of conducting an independent inspection. In addition, an inspector meeting series is conducted every other Wednesday during which all of the inspectors gather to share experiences ideas, et cetera. There is a rotating responsibility for these meetings, with each these inspection team in turn taking charge of one of the meetings. Meetings may include a briefing on recent inspections that addresses problems encountered, a guest speaker to discuss issues related to select agents, et cetera. While training activities are in place, there is a lot of room for improvement. One way to do this is with the development of core internal faculty comprised of SMEs. DSAT agrees with DSI that there is a need for additional expertise in the area of biosecurity, and is in the process of recruiting for a biosecurity specialist. DSAT is also looking to leverage its training against some excellent existing programs. DSAT's inspectors are already required to complete the Emory University Containment Training Program. A list will be developed of other excellent external training programs in the areas of biosafety and biosecurity that will be made available for DSAT inspectors. The ultimate, though lofty, goal is to develop the DSAT training program to a point at which there is a core group of senior federal inspectors who would qualify for certification as biosafety professionals.

In terms of moving forward on recommended program improvements, a follow-up DSAT Leadership Retreat will be convened in the Fall of 2009 during which they will review progress

on January 2009 objectives; and incorporate HSI recommendations not specifically addressed in the January 2009 planning. This will be moderated by COTPER's Strategy and Innovation Office.

Dr. Weyant stressed that there are many other drivers for change in DSAT. It has been approximately a year since the FBI's Amerithrax report, which implicated a scientist at a federal select agent laboratory as the most likely perpetrator of the Amerithrax mailings. This has caused a tremendous amount of concern in Washington. The following, though probably not complete, is a list of advisory groups that have been established by either the Executive Branch or Congress to examine biosafety and biosecurity in the United States:

- ☐ Trans Federal Task Force on Biosafety
- ☐ EO 13486 Working Group on Strengthening Biosecurity in the US
- ☐ Weapons of Mass Destruction Commission
- ☐ National Science Advisory Board on Biosecurity
- ☐ National Academies of Science
- ☐ Defense Science Board
- ☐ Congressional Research Service
- ☐ Government Accountability Office
- ☐ Select Agent Program and Biosafety Act of 2009
- ☐ Proposed Weapons of Mass Destruction Act of 2009

Dr. Weyant elaborated on a few of these. The Executive Order 13486 Working Group on Strengthening Biosecurity in the US group was established on January 9, 2009 by then President Bush. This group was tasked with reviewing overall biosecurity in the US, identifying gaps, and making recommendations. DSAT worked extensively with this group to establish a series of recommendation, which were provided to the White House on July 9, 2009. The Weapons of Mass Destruction Commission (WMD) testified before Congress regarding their concerns about a biological attack. The Government Accountability Office (GAO) has conducted at least two studies regarding select agent issues. Pending legislation known as the Select Agent Program and Biosafety Act of 2009 has been read into both the House and Senate. This act would require DSAT to strengthen the Select Agent Program in the area of biosecurity, have greater interaction with colleagues in DHS, and strengthen outreach efforts. There is also a Proposed Weapons of Mass Destruction Act of 2009 being crafted by the staff of the Senate Homeland Security Committee. While its contents are currently unknown, it is anticipated that this act will also propose improvements to the program. Thus, the HSI study represented only one driver to improve DSAT's work. DSAT suspects that in fall and winter, the White House will engage in a policy process to assess all input and provide additional guidance to DSAT.

Discussion Points

A BSC member requested further information regarding inspection, compliance, and authority to issue violations.

Dr. Weyant replied that DSAT's inspectors have checklists that are related specifically to the regulation. For example, the regulation requires that an entity have a security plan in place that is multi-tiered, is based on a risk or threat assessment, has been trained to the staff, and is being executed. The regulations call for a review on an annual basis. The inspectors assess whether there is supporting documentation to substantiate that the plan has been executed

(e.g., access records, training records, et cetera). In the past year, DSAT has taken this a step further to interview staff members regarding how well they understand this. The regulations were written primarily by staff at CDC and APHIS, although they go through a comprehensive review process at HHS, USDA, and OMB. The enabling statute tasks the Secretaries of Agriculture and HHS to do this job, so ultimately the regulations are published through the Secretaries.

A BSC member requested clarity about the recommendation that inspectors be more acquainted with risk assessments.

Dr. Salerno responded that the rule is relatively short, and focuses on control and accountability of pathogens. However, it refers by reference to the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) manual. The BMBL is a set of guidelines and was never intended to be regulations. Neither was it approved as a regulation; however, it is referenced within the rule. This has presented a unique challenge to the program and the regulated community. HSI observed that the extensive checklists developed by DSAT reflect the details required in the rule and many of the guidelines that appear in the BMBL. The regulated communities sometimes feel that they are being regulated to the guidelines. This makes it difficult for the inspectors to determine what constitutes compliance. Regarding risk assessment, if the BMBL is part of the regulatory inspection process as it is currently, it explicitly instructs laboratories to design either a safety system or a security system based on a risk assessment. From Dr. Salerno's perspective, this places responsibility on the inspectors not to necessarily assess all mitigation measures, but also to compare the mitigation measures in place at a facility with a risk assessment that was created by the facility. This is a complex challenge and is a difficult expectation for inspectors to do in a one- or two-day visit to a facility that they have not seen in one or two years.

A BSC member requested clarification about the difference between biosafety and biosecurity. Given that it appeared the BSC would vote on the 29 recommendations as a block, this member also requested that Dr. Weyant indicated whether DSAT agreed with all of them and if not, to state those with which they did not agree.

Dr. Weyant responded that although DSAT did not agree 100% with everything stated in all 29 recommendations, there were no recommendations to which they were significantly opposed, or which they felt were inappropriate. Dr. Weyant repeated the definitions of biosafety and biosecurity: The goal of biosafety is to protect workers, the public, and the environment from exposure to hazardous biological agents. Biosafety is achieved through a series of training of staff, application of appropriate safety equipment, and application of containment devices that separate the staff from the organisms. The goal of biosecurity is the science of protecting select agent materials from theft, loss, or release. In order to achieve biosecurity, the materials have to be contained and sequestered in such a way that access to such materials can be effectively controlled. There is significant intersection, so it is fortunate that many of the tools used to achieve biosafety also help to achieve biosecurity.

Dr. Matthews pointed out that the easiest way to separate biosafety from biosecurity is that biosafety is concerned with the unintentional, accidental release of an agent from the laboratory either by infecting one of the workers or release into the environment. Biosecurity is the intentional theft, loss, or release.

Dr. Salerno added that biosafety is protecting people from bad bugs, while biosecurity is protecting bugs from bad people.

A BSC member suggested that the training aspect of the program could probably be expanded. The concept of shadowing is a good one, and could probably be formalized. Inspectors could be trained in coaching, for example. There are a number of instruments available, such as one developed by the Gallup Organization called StrengthsFinder 2.0, which determines the talents of the individual. This is a very inexpensive program for which a book can be purchased and the instrument can be completed on-line. This helps in talent management, which is a very critical part of coaching. There are also many training opportunities after someone is hired. For example, perhaps an annual risk assessment and methodology update could be planned.

A BSC member pointed out that within the comprehensive list of 29 recommendations there seemed to be a combination of strategic, tactical issues, and management and operational issues. Aside from the BSC focusing on assessing how well science is being applied to the management and strategy definition, this member did not believe it was prudent to micromanage any aspects of the recommendations. Perhaps DSAT should consider which five recommendations were most likely to be doable and to have the highest impact in the next year or two.

Dr. Diaz replied that the 29 recommendations could certainly be grouped into 6 or 7 areas. He stressed that the review group was not driven to consensus of a rank ordering, given that all of the recommendations are important. A challenge as an FFRDC in conducting program or process improvement reviews is that once a group of experts is assembled to make recommendations to the government, other concerns arise such as bringing in the public, having open meetings, et cetera. Therefore, they basically permit the experts to speak their peace and then it is left to the program to determine what is most important to their mission. The issue about which the reviewers seemed to feel the most strongly throughout was biosecurity. While one SME felt very strongly that DSAT needed to re-examine its mission, quite a few SMEs did not feel that this was highly important because this is typically the way the government writes their mission statements.

Dr. Weyant responded that he thought it was important for DSAT to retain some flexibility to respond to these recommendations, as well as those coming from all of the other studies that have been done. It was not clear to him whether the BSC could vote to support this document as a whole, or if it would add value for COTPER or DSAT to have the flexibility to assess these recommendations in conjunction with future recommendations that are made before the next BSC meeting.

Dr. Popovic added that part of the process for the BSC allows the program to respond in a way that says exactly what Dr. Weyant stated. Dr. Frieden has consulted regarding the BSCs because it is important to understand whether this is going to be a continuing process with the new director and changes he is considering. He is extremely interested in recommendations being made, but the program is entitled to respond to them. A response does not have to be made to every single recommendation. The program can simply state that a recommendation is reasonable and doable from its perspective. Flexibility is inherent in the process. CDC is also in the process of providing more guidance on how the recommendations are going to be made available to the public on the webpage, how the agency will be monitoring the responses of each program, and within what time frame responses are expected of programs.

Dr. Sosin added that in many ways, COTPER already takes that strategy and approach, but will adapt to whatever the agency approach is. While none of the recommendations are unacceptable, having flexibility must be built in. There are financial and timeline issues in addition to the need to how well COTPER can respond and what is prioritized in the programs. Dr. Weyant basically showed where DSAT's priorities lie. This session represented an opportunity to obtain additional input from the BSC, such as the suggestion made regarding the expansion of the training recommendation.

An *ex officio* member found that the comprehensive and thoughtful report dovetailed very nicely with some of the other federal efforts in which several of the BSC members had been involved pertaining to biosafety and biosecurity. It sounded as though the message from the White House was that they wanted to begin an interagency policy process through which they would examine all the reports, meet for discussion, and eventually decide what the policy position of the US government would be. With that and current resources in mind, this member wondered whether there was any "low hanging fruit" DSAT could tackle immediately? There is also draft legislation on Weapons of Mass Destruction (WMDs) that will soon be open for comment at the departmental level.

Dr. Weyant responded that some of the "low hanging fruit" was encapsulated in some of the objectives on which DSAT was already working. The review of NSAR could probably be completed within 120 days or so. Keeping their colleagues in Agriculture in the loop, depending upon the results of that review, DSAT could plan its next steps based for upgrades to the system. With the continued move toward electronic file management, they already have a good start. The establishment of a more comprehensive training program could at least be fleshed out in the next six months, at which time they could begin to move inspectors through the program.

A liaison member wondered what the implications would be for safety and biosecurity if some of the recommendations were not put in place going forward. This member also inquired as to whether DSAT engaged in mock training drills, and what their relationship was to the academic institution Level 4 labs, the DoD, and the Defense Intelligence Agency (DIA).

Dr. Weyant responded that with respect to DoD and academic institutions, the statute that serves as the fundamental basis for the DSAT program is very clear in its mandate that if someone uses, possesses, or transfers select agents, they must register with the CDC or USDA. As part of DSAT's inspection process, an annual drill is required for every entity in the areas of biosafety, biosecurity, and incident response. They must document what was done, when it was done, who was involved, who was trained, et cetera. DSAT does review the records for these drills. DSAT could evolve toward the establishment of some best practice guidelines. As they go around the country, they have great opportunities to observe various approaches to meeting these requirements. DSAT has a long-term goal to develop broad, generic guidance in the area of drilling or table top exercises. They also have robust incident report data, about which they would like to draft a review by the end of the year. With respect to relationships with others (e.g., DoD, others) DSAT regulates all labs that have select agents, applying the same regulatory standards to those as are applied to others. There are compliance issues, and DSAT prosecutes non-compliance in those labs with the same rigor as they would any other lab.

A success story was shared from a lab operation that quickly ramped up in another facility in order to be able to better handle influenza, which risked being badly compromised given the influenza group's small facility. There was an iterative, negotiated process that involved security

and safety, but was navigated by a group of humans working together—not just regulations and rules.

A liaison member pointed out that while the review and presentations were comprehensive, they were not very compelling. This member wondered how they might generate and maintain excitement for DSAT such as the 2002 anthrax outbreaks and perpetrators generated. The term “select agent” itself is boring. Perhaps it could be changed to “deadly microbe” to make it more exciting. Most people dealing with these agents will comply with the regulations and are innocent good guy citizens who at the most might be careless but are certainly not bad guys. The proposed perpetrator who committed suicide still “slipped through the cracks” of the system that was HHS-oriented. Although the air traffic control system could not have protected the US from attack against the Towers on 9/11 towers because that was bad guys, it is still something everyone is comfortably taking for granted. Presentations like this in which data indicate that there are 74,000 laboratories in the country that are dealing with $\times 10^6$ select agents that are potentially injurious, and there are 1.3 million technicians who have received training, makes everyone feel comfortable like air traffic control. Also troubling is that CDC shouldered a lot of the burden and took a lot of the blame for anthrax when it was primarily due to a bad guy, not a bad microbe or an unsafe system. The idea that there can be protection against crazy people with being open about it is preposterous. Consideration must be given, openly, to what is being done to protect people against the next crazy person at Ft. Detrick, CDC, or someplace else.

Dr. Weyant responded that many of these concerns have been expressed, especially in the last year. It is important to remember that regulations were promulgated after the Amerithrax attacks. Fortunately, there has not been anything similar and a cause-effect relationship could not be proven though there is a healthy association. In terms of creating more interest or more visibility of the program, significant resources have been put into outreach. An ongoing series of select agent workshops is underway at CDC, in partnership with USDA and the Department of Justice (DOJ). Over 100 people attended the most recent workshop in Atlanta, and a webinar was set up with a couple of hundred more participants. That one event potentially reached about 50% of the regulated community. It was also open to the public. The great importance of the DSAT program is that if it is successful, critical biodefense research can be conducted to better protect this country, and it can be done in such a way that the neighbors of these institutions can feel confident that the work is being conducted in a safe and secure manner. This is how they try to sell the program. Dr. Weyant has made 30 trips to Washington in the last year, meeting with Congressional staffers and the committees that have an interest in this work. He believes that they consider the select agent programs to be a good, knowledgeable, and honest source of input for reasonable legislation. Thus, DSAT is having some success, although more can be done to get the message out.

A liaison member added that the public is primarily concerned about incidents. The concept of having incident response, which may be a different division, is an important message in describing the program. That is, the concept that CDC has an incident response that goes along with the select agent program is comforting to the public.

At this time, Dr. MacKenzie called for a vote on the 29 HSI recommendations.

Motion

A motion was made and seconded to accept all 29 of the HSI recommendation in a consolidated manner, with the understanding that CDC / COTPER / DSAT will respond. The motion was seconded, with 6 BSC members approving, 2 opposing, and 0 abstaining.

Discussion Points

- ☐ The recommendation should be with the understanding that CDC will respond in the ways outlined by Dr. Sosin.
- ☐ The recommendations include: efficiency of operations and effectiveness of the program. It is difficult to determine within the 29 recommendations what will constitute improvements in the effectiveness of the program. The program appears to be efficient, but deficiencies in the effectiveness of the program are unclear.
- ☐ The report seems to lack what science and technology can be utilized to improve the program. An example to address to improve effectiveness and efficiency would be to use information technology to acquire daily information about what is occurring in each location rather than only assessing this once every year or two (e.g., use technology to review of the technologies and science that exists in order to acquire, analyze, and process data and turn it into information). This could be a part of the strategic planning process.
- ☐ What is missing is a consolidated, concentrated set of recommendations from the BSC that they were not given ample time to do. This was one of the reasons for asking Dr. Weyant what he envisioned as the top 5 most important recommendations.
- ☐ A business process analysis could be part of that strategic planning process that would leverage where DSAT is going. This could save money, improve efficiency, et cetera.
- ☐ It was clarified that the motion did not regard whether the report was good or bad. Instead, it was meant to make a motion that the group vote on the 29 recommendations as a block and discuss the report as a whole, versus voting on each of the 29 recommendations individually. It was not clear whether those who were opposed objected to the motion or the substance of the report.
- ☐ Some degree of deference must be given to the fact that they seemed to be working from a deconstructed model.
- ☐ Clearly this report was contracted and developed to report back to CDC; however, it is missing context that would explain to an outside reader what the overall objectives are (e.g., size of the system, how many labs, how many people have access, the number of agents is listed in the appendix, where are they, what quantities, scope of the program, et cetera).
- ☐ Add the strategic planning pieces and the broader analysis mentioned following the first vote. Two BSC members agreed to write specific language to this effect. It appeared to some members that this would strengthen Recommendation 2.
- ☐ Dr. Weyant indicated that there is a comprehensive review of the NSAR, although the full extent of it is not yet known. He also stressed that the report including the 29 recommendations was in the context of many other efforts under consideration.

- ❑ The Technical Monitor on that assessment indicated that the deliverables are a strategic 5-year approach for IT solutions that can help foster the business. It is not intended to be a comprehensive, all-business, strategic IT initiative.
- ❑ Dr. Sosin thought it was fair and appropriate for the BSC to make a statement about this being an assessment of current business processes pertaining to a current model of biosafety and biosecurity, and that they believe it is important that there be a broader examination of alternative approaches that might be more effective and more efficient.
- ❑ The BSC can go ahead and vote on the report as a whole, with a caveat that the amendments will be included. The Board cannot change the report, but can vote yes or no and suggest amendments to the report that would be communicated back to COTPER staff.
- ❑ Dr. Popovic stressed that CDC has the recommendations, and that it was important to actually vote during this meeting unless there were major objections to the report. If there were no issues of trust, the Board should vote simultaneously to approve the report with the inclusion of the Board's comments.
- ❑ If this is public record, is regulated, and the additional language being worked on by two BSC members becomes a BSC recommendation, the group should see it and vote on it rather than just having it out in the stratosphere.
- ❑ Though suggested that this could be done by email, some members objected given the difficulty in crafting the exact language in that manner. This requires discussion and a vote during this meeting. COTPER is investing a lot of money to have the BSC's recommendations, which was the crux of this two-day meeting, so it should not be done in a sloppy manner.
- ❑ Perhaps the two Board members who agreed to craft the additional BSC language could do so during the lunch break to be presented to the full BSC in the afternoon.

Amended Motion #1

A friendly amendment was made to the motion to clarify that the motion was to discuss the 29 recommendations as a whole, with additional BSC recommendations to be made based on the discussions. The motion was seconded, with 8 BSC members approving and 0 abstaining.

Subsequent to the lunch break, the following amended motion was made:

Amended Motion #2

A motion was made and seconded to adopt the following language as the COTPER BSC's recommendation, in addition to the HSI report:

The context of recommendations for DSAT is improvement of current status-quo operations with emphasis on improved efficiency. Recommendations do address strategic planning process, but do not address improvement of effectiveness of DSAT mission—focuses primarily on efficiency thereof. As such, the BSC recommends that in the coming years DSAT:

- a. Elevate the priority of strategic planning processes that define the strategic context – critical objectives, vision, outcomes, impact (e.g. cost-benefit analysis), and effectiveness. This will likely retarget efficiency and effectiveness improvement initiatives.
- b. Explore the use of emerging information technology advances to acquire in a real-time manner activities of all entities that it oversees.
- c. Create system-wide business processes and performance outcome analyses in the context of b.
- d. Develop tools that provide improved analysis, decision support, and added value to both DSAT operations as well as stakeholders (i.e., registered entities) taking advantage of information system technologies.

The motion carried with 8 BSC members approving and 0 abstaining.

Discussion Points

The following discussion points were made that ultimately led to the above motion and vote:

- ☐ Concern was expressed that the way 1A was stated suggested that they were attempting to get Congress to amend the statute, which did not seem like what they really wanted to do. Saying that they should “elevate priority of strategic process” only clarifies mission, and it is not clear that the BSC has any control of that. The statute controls the mission.
- ☐ It was clarified that they were not trying to suggest that Congress amend the statutory language.
- ☐ Mission means the same mission clarification that the report referenced. The report said the mission needs clarification.
- ☐ Perhaps it meant to add language to better explain the mission without changing the statement of the mission.
- ☐ Since the report already addresses clarification of a mission, just eliminate the word “mission” from this motion.
- ☐ Take out the word “mission” and state, “Elevate priority of strategic planning process that defines the strategic context . . .”
- ☐ Use the word “vision.” State, “critical objectives, vision, outcomes, impact.” That would allow freedom to define direction.
- ☐ Concern was expressed regarding 1d regarding “analysis tools based on search engine technology,” given that this seems too prescriptive. Some panelists felt that b, c, and d were too prescriptive.

- ❑ There was also concern with the inclusion of examples, given that they be misinterpreted as requirements. Perhaps the “for examples” could be deleted.
- ❑ Being too general will not make any contribution. An e.g., in parentheses should not be too binding.
- ❑ It was not clear to all members that “develop analysis tools with the goal of improving awareness and gaining knowledge of emerging threats” was the function of the select agent program.
- ❑ Dr. Weyant clarified that the goal of improving awareness and gaining knowledge of emerging threats is an “icing on the cake” concept. The core mission is regulatory oversight as mandated by Congress. That being said, DSAT has been thinking about the data it receives and how that could add to the greater mission of COTPER and CDC. Consideration is being given to a geographic information system (GIS) based system to look for clusters. They have already established partnerships with the Center for Infectious Diseases (CCID) to share reporting data to help the overall CDC surveillance program. The ideas are all good, but the board must remember that they have to be prioritized in the context of the mandate and resources.
- ❑ Dr. Sosin agreed that there had to be a balance between asking COTPER to do things that they could not possibly address, and putting ideas on the table that would allow them to think differently, and bring back a reasonable response regarding how the ideas will be explored. Day to day activities clearly have to come first for DSAT. 1d was getting at the notion that there is some uncertainty regarding whether unregistered entities are in scope or out of scope. At the same time, DSAT decided that they are going to monitor the literature to determine whether they can identify entities working with select agents that should not be doing so. The Board is saying that while this is a good idea, it could be broadened by searching the internet more broadly than just the biomedical literature.
- ❑ It was suggested that consideration be given to sequencing this kind of a process through from the current scenario to where DSAT wants to be in 3, 5, 7, 10 years, particularly given emerging technology. Consideration should also be given to the fact that fewer resources are now required due to open standards, open source software, and open source solutions. Add that the context of the recommendations for DSAT is improvement over the next 5 years of current stages.
- ❑ 1e regards emerging pathogen threats that are not on the list, as well as threats to biosecurity of facilities that are using select agents.
- ❑ Dr. Weyant expressed concern about getting into a circular argument. The way the statute is written is that DSAT develops a list of select agents and then regulates based on the list. Asking them to identify emerging threats that are not on the list would be asking them to develop a surveillance system that is based on detecting agents outside the select agent list. These are agents for which DSAT has no statutory authority to regulate. They are screening the literature for specific select agent work that may be done in places that are not registered for that work, but with agents that are already on the list. The list of select agents is periodically reviewed with input from SMEs.
- ❑ It was suggested that language for 1e be changed to “identifying unregistered entities working with select agents.”

- ☐ Concern was expressed about how they were going to balance the interim process, the validation of the interim process, and also the outreach to effectively safeguard the community as part of the process. It was noted that this comment was not to propose a specific recommendation, but was instead to get this statement on the record.
- ☐ Dr. Weyant expressed his hope that item 1d did not put DSAT in the position of being expected to identify every criminal who is trying to do something in his garage.
- ☐ Dr. Sosin pointed out that responsibility for unregistered agents is somewhat “fuzzy.” DSAT has also taken the approach that this is the good guys who just do not know they are supposed to have special rules and regulations.
- ☐ It was suggested that 1d be removed and the analysis place in 1e to read, “develop improved analysis, decisions explored, and value added . . .”
- ☐ There appeared to be consensus that 1e should be deleted, and 1e should move up to 1d.
- ☐ Some members remained troubled with the e.g., list in 1b and suggested taking it out.
- ☐ It was suggested that they could add language to the opening paragraph to read, “As such, the BSC recommends that in the coming years DSAT: a. Elevate the priority of strategic planning processes; examples that DSAT might consider are: 1) explore the use of emerging information technology, 2) create system-wide business processes, 3) develop tools . . .”
- ☐ Sentiment was expressed that they were now watering down the recommendations, and they no longer had any “teeth.” Others felt it was still a good recommendation. All of the recommendations will have to be vetted with the DSAT, and DSAT will respond to the board to offer their impressions of what is doable, what they agree with, and what they do not agree with.
- ☐ Concern was expressed that the examples may be interpreted as the only things being recommended rather than simply being examples.
- ☐ Change 1d to read “analysis, decision support, and added value.”

BSC Peer Review Topics for FY2010 / Meeting Structure

Ellen MacKenzie, Ph.D., Member, COTPER BSC

**Barbara Ellis, Ph.D., Deputy Associate Director for Science, COTPER
Designated Federal Official, COTPER BSC**

Dr. MacKenzie reminded the members that the previous day they were supposed to have discussed the focus of the peer reviews for FY 2010, as well as the recommendation by COTPER to cutting back to two instead of four reviews per year. She suggested that any lengthy discussions about these issues be tabled, given the time constraints. Deliberations about the topics could take place via email or teleconference; however, she suggested resolving the issue of the number of reviews per year during this meeting. In addition, she suggested spending a few minutes entertaining any general comments about how the BSC meetings are currently being run and structured.

Dr. Ellis reminded everyone that the previous day they had heard from three of COTPER's four Associate Directors for Science regarding peer reviews that are at various points of progress. She thanked their ADS staff for their leadership, pointing out that these program reviews represent a considerable amount of work. External peer review of COTPER's programs is new for this relatively young organization, and while in the beginning they believed that four program reviews annually would be sustainable, they have come to realize that is not. One review that will be conducted in FY2010 will be of the Division of Emergency Operations (DEO). While external peer review of COTPER's programs is an incredibly important function of the BSC, the board has other functions as well. COTPER does not want the external peer reviews to be so cumbersome that they fill every agenda of every BSC meeting. They would like for the meetings to have ample time for activities, such as the "Ask-the-Board" during which COTPER could hear more in the way of strategic advice from the members. Hence, limiting external peer reviews to two per year would free up the meeting agendas to discuss about other issues. In conclusion, Dr. Ellis noted that the COTPER specific guidance was revised. It is a living document that is anticipated to be revised annually. As part of that update, some of the appendices were simplified, such as the removal of one that was no longer applicable and the additional of one that provides an outline for ad hoc workgroup reports.

Discussion Points

A BSC member inquired as to how many programs total would need to be reviewed, and how often would COTPER like them reviewed.

Dr. Ellis responded that the BSC briefing document included the CDC policy on peer review, which mandates that programs are to be reviewed once every five years. How a program or activity is defined is flexible, given the guidance earlier from Dr. Popovic. Whether they could get through all of them within that five-year period would depend upon how they define programs or activities. A list of proposed topics was also provided in the COTPER guidance document. The language states that at least two peer reviews must be conducted annually.

Several BSC members agreed that four reviews was too many, based on attempting and failing to complete that number the previous year.

A liaison member inquired as to how the findings of the BSC affected COTPER's federal funding cycles; that is, are there certain time periods by which efforts must be completed in order for COTPER to allocate funding according to programmatic areas, and how does this affect CDC's overall request for federal funds?

Dr. Ellis responded that she did not think there were. COTPER takes the recommendations approved by the board extremely seriously. All recommendations from the board must be put into a General Services Administration (GSA) FACA database. The Office of Management and Budget (OMB) examines and monitors percentage of recommendations that are actually implemented and if not, why not. On an annual basis, programs will report to the BSC their progress in implementing recommendations that have been made. For example, Dr. Lindsey reported the previous day on the FAP external review.

Motion

A motion was made for the BSC COTPER to engage in at least two (2) external peer reviewers annually. The motion was seconded, with 8 BSC members approving and 0 abstaining.

Turning to the issue of the structure of meetings, a BSC member inquired as to how useful the previous day had been and whether CDC had gotten as much out of it as hoped. Given the number of presentations, the board was largely passive.

Dr. Ellis agreed that it would be beneficial to have more strategic discussions about some targeted issues in the future.

It was noted by a BSC member that the two webinars repeated almost verbatim what was on the handouts that were sent in advance, with little discussion. Thus, the webinars are not particularly useful. The time would have been better spent with the BSC posing questions about the programs and engaging in discussions about the programs. The process that has been used does not evoke a lot of response. Nevertheless, it was important and useful to understand what COTPER does. Now that most members have a reasonable understanding of this, such information should probably be dispensed with.

Other members felt that the previous day had been very useful, pointing out that there was a period of time during which they should not be giving advice until they know more.

A BSC member inquired as to whether COTPER felt that the right disciplines were represented in the membership of the board and in the liaisons representing other departments or agencies, or whether some disciplines or agencies may be missing based on anticipated activities. For example, perhaps a liaison or *ex officio* member should be added from the USDA to help address select agent issues.

Dr. Sosin pointed out that they were not revisiting the scope or the charter of the BSC per se. There are constraints with respect to scope, expertise, size versus a tighter group, et cetera. The BSC is not expected to be able to provide all of the advice that COTPER will need. Through the BSC, COTPER is attempting to have at least one formal forum that is flexible,

adaptable, and well-understands the program. He agreed that there were a number of other groups with whom they could work, but they must draw the line somewhere. The current membership seemed like the right size for an interactive group to deeply understand COTPER. Occasionally, additional expertise or representation may need to be included in these meetings, to which COTPER is open. The Board is lacking three critical disciplines that they would like to fill (e.g., epidemiology, medicine, laboratory). Regarding meeting format, to some degree, he thought the previous day went very well because he learned a lot in the process of listening. He felt that there had been ample time for good discussion. Clearly, they need to make more of that and less of the slide presentations. He thought the idea of posing questions for the Board to deliberate was a good one. He stressed that COTPER was flexible in terms of the format and schedule of the BSC.

Dr. Ellis added that they were not talking about changing the functions of the Board. Providing strategic advice is part of the BSC's responsibilities, and all CDC BSC charters are standardized. Secondary review of grants and contracts is listed as a function of the board, which has been a challenge to accomplish in this group. There was not a quorum because a number of Board members had conflicts of interest. Nevertheless, as a part of current charter COTPER hopes their role can be expanded to engage in this function.

It was suggested that because COTPER is engaged in emergency response, it might be helpful to have somebody a state or large local health department who is in charge of emergency response.

Liaison members pointed out that it would be beneficial for them to be told in advance if there was any information they needed to prepare to present during BSC meetings.

Updates from Liaison Representatives

Association of Public Health Laboratories (APHL)

Mary Gilchrist, Ph.D., D(ABMM)
Consultant, Public Health

Dr. Gilchrist expressed her great enthusiasm for hearing CDC's new director, Dr. Frieden, and also Dr. Sosin express their support of the laboratory side. She is no longer running a lab, so she does not have a vested interest, but because she did this for a long time she remained interested. It seemed to her that the H1N1 outbreak demonstrated the need for the Laboratory Response Network (LRN). State and other public health laboratories pitched in as soon as the tests were made available in order to run tests in the states. While this demonstrated capacity to address the situation, it also demonstrated the need for improvements. There may have been opportunities for some laboratories to move faster and increase their surge capacity. She thought a strategic plan was needed that would encourage everyone to understand where they needed / wanted to be. Perhaps a vision for the future is needed for the LRN that changes it substantially. Although she was an architect of the LRN, she would still like to see it change somewhat. She suggested considering some benchmarks regarding the expectations labs should meet. States do not always distribute funding to labs as they should. Over the 10 years or so of the existence of these labs, there have been great successes, but continued improvements are needed.

Association of Schools of Public Health (ASPH)**James Curran, M.D., M.P.H.****Dean, Rollins School of Public Health; Co-Director, Emory Center for AIDS Research
Emory University**

Dr. Curran indicated that he represents the 41 accredited Schools of Public Health. ASPH has been involved with Dr. Williams-Johnson with the Centers for Public Health Preparedness and also the PERRCs, as well as with Dr. Young on the Competency Project. His main message was that these centers have provided a very unique opportunity to work with state and local health departments and the preparedness communities that is extremely rare. When he left CDC to go into academia, he found that there was a dearth of funding for public health training and for partnerships with state and local governments. That is in contrast to the billions of dollars for medical training and nursing training, and the \$30 billion at NIH for research. Thus, it stands to reason that schools of public health, like medical schools and other parts of universities, look to NIH for their research dollars. However, NIH is a very clinically oriented prevention place that does not really permit partnerships with health departments or with community agencies and the research point of view that this brings. COTPER's centers, along with CDC's Prevention Research Centers and a couple of other areas, provide really a unique opportunity to engage in that kind of research.

Universities have their limits as well. They are primarily oriented toward research and training and not as oriented toward service. However, their strength is that they are very flexible once inside. For example, faculty members are entrepreneurial. Emory's PERRC grant, for example, involves three different parts of the university. It is not necessarily thought of as a public health grant because it involves the Emergency Medicine Department, the University Operations Center, and their Incident Response Center. He encouraged COTPER to continue to think of these centers as windows to universities and the 41 schools of public health involve, which are all located in the top 50 to 60 largest medical schools and universities in the country.

He also stressed that they should be patient with the research endeavor. Unlike evaluations, it is very difficult sometimes to target research efforts, like a randomized trial, and many of the most innovative ideas may not necessarily produce the answers wanted or any answers. That is the nature of research. Often he hears from practice partners, "But, we just need some research to show that this works so that we can do it." Of course, as the Board knows, that is not how it works. Conversely, research may result in findings about things that really work that no one realized. This is an exciting opportunity to expand this area in preparedness research, and a model for CDC which ASPH hopes to be a much larger program.

Association of State and Territorial Health Officials (ASTHO)**Damon Arnold, M.D., M.P.H.****Director, Illinois Department of Public Health**

Dr. Arnold indicated that he was representing ASTHO. He said he was overwhelmed with the amount of time and effort put into constructing this meeting and how beneficial it was.

ASTHO wants to ensure that there is no loss in some of the great improvements gained over time, to make sure that they are consistently following some of those same paths they have

been following, and to make sure that there is ongoing structured communications. ASTHO was extremely pleased with CDC's response to the H1N1 situation on a local level. Many times people forget that the local health departments are at ground zero. They are sitting there waiting for assistance. CDC reached out and did that very well during the H1N1 effort.

ASTHO would like for project officers to be designated to sites for longer periods of time, so that there is moving around and turnover of project officers, and to build on the public health infrastructure within state and local health departments. More guidance on the construction of internal processes within the departments is also needed. Of course, everyone needs financial support. The federal government needs to understand that CDC is essential globally, as well as at the local level. There is a tendency to think of CDC as being "out there somewhere," but they are actually present within small towns. Support is really needed from the federal government to make sure that the adequate funding is supplied to meet the needs of these projects that are vital to survival.

Also, there is a need to delineate and make more clearly distinct the borderline between the CDC with the ASPR regulations, the ideas between the two, and how to clarify those to a better degree. ASTHO is also concerned about the National Public Health Security Strategy and how they fit into that process. It is important to consider the surge for the fall and to stay focused on those issues; however, it is also important to understand that states have other pressing issues. Last year, Illinois had 86 natural disasters. He kept telling his staff that those disasters would not go away—they are seasonal and would be coming in the fall along with H1N1. So as states begin stretching their resources to deal with H1N1, so too will they have to respond to other underlying disasters as they occur.

ASTHO would like grant cycles, if possible, to be increased to 3 to 5 years, because short cycles of only one or two years become part of the legislative process rather than being a projection strategy for public health implementation in the long haul. It is very difficult to put long-term goals in place with short grant cycles.

Council of State and Territorial Epidemiologists (CSTE)

Patricia Quinlisk, M.D., M.P.H.
Medical Director and State Epidemiologist
Iowa Department of Public Health

Given that Dr. Quinlisk had a conference call, Dr. Karen Smith reported on her behalf. Speaking on behalf of the CTSE, something that they have been both struggling with and working on for the long-term is the translation of surveillance in its traditional sense in public health into this emergency preparedness type of surveillance—actually now, melding the traditional seasonal influenza surveillance to incorporate the new challenges posed by H1N1, and the fact that it is coming more quickly, it is surging at different times, and it is in different populations, all of which complicates the issues of a system that has been preexisting and now needs to be adapted, and adapted in a very fluid way. Consideration also must be given to how to explain this to the public.

CDC, as much as any other agency, encountered what happens when trying to change how a disease is reported on. They began by reporting case numbers, but then decided that was not very good for good scientific reasons. However, the public still wanted to know about case numbers. Just in that example is the issue of communications and how to communicate epidemiologic information to the public in a way that is useful, and also hopefully not able to be

used in a misleading fashion by others, particularly to hype issues out of proportion. That is, to some extent, inevitable, but perhaps everyone can do a little bit to keep that from happening.

Tactically speaking, the coordination of the seasonal flu vaccine campaign and the H1N1 campaign are going to be logistically very difficult, and it will be very difficult for epidemiologists to track anything about efficacy, number of doses, et cetera. This is a huge logistical challenge for the epidemiological world. The same issue exists, obviously, with the use of antiviral agents and looking for adverse events in both circumstances, whether it is a vaccine- or antiviral-related event. They should use some of the IRIS immunization models.

Dr. Quinlisk returned at this point, and explained that IRIS is an immunization registry. The suggestion would be to use the IRIS or other immunization registry systems not only for monitoring the doses given and having good information about how the vaccine is being used, but also perhaps to recall children for second doses. Another issue that has arisen is isolation and quarantine. There is a lot of concern from the public currently about how those are going to be used. In Iowa, they sometimes put signs on the door. There is a lot of concern from the public about stigmatization, especially in terms of how that might be used.

Through the natural events that occurred during the spring, much more was learned about real life of how things respond and things are done. She assumed that as they moved into the fall, they would learn increasingly more about how to respond and what is occurring, particularly working with partners. While everyone knows that it is really important to learn from that, it would be beneficial to know the lessons learned at all levels (e.g., local, state, federal) and understand how this can be translated to other events (e.g., anthrax, chemical spills, natural disasters, et cetera). This is especially important because this is the first time that partnerships have been forged with groups such as schools. They should not lose sight of the "big picture" issues because of dealing with one particular virus.

This has become an opportunity, especially for smaller health departments like Iowa, for cross-training. When an event such as H1N1 occurs, a lot of non-infectious disease people are brought into the area to learn about it. There should be training in areas that normally, on a day to day basis, would never be involved. Not only does this provide an opportunity to get the infectious disease people fully up and going, but also it expands the ability to respond to any type of event because people across the board, across departmental lines, are being trained.

National Association of County and City Health Officials (NACCHO)

Karen Smith, M.D., M.P.H.
Public Health Officer and Director of Public Health
Napa County Health and Human Services Agency

Dr. Smith said it was an honor to be able to speak on behalf of NACCHO. NACCHO is engaged in two levels of work surrounding emergency preparedness: very strategic work and some fairly detailed tactical work.

Strategically, there are over 3,000 local health jurisdictions in the US, and NACCHO works very hard to try to explain to people the scope, not just of the diversity, but the commonalities across those rather than having everyone just throw their hands up and say, "We just can't work with health departments that range in size from 3 people to New York City." NACCHO has been working very hard for the past few years on the establishment, adoption, and dissemination of standards and metrics for public health emergency preparedness. Dr. Singleton referred to

“Project Public Health Ready” which is a very systematized process of local health jurisdiction assessment of their preparedness. That has now been adopted by several states, in a statewide fashion, and is being currently adapted for regional application as well.

NACCHO is trying very hard to bring the science, the system science of public health, to the emergency preparedness part of that and then blend it into the rest of what public health does. Similarly, they have created, through the new accreditation process, the voluntary accreditation of local and statewide health departments. They have worked on the standards for the accreditation, especially around public health emergency preparedness. They are continuing to try to both describe, but also study, what it is that health departments do with respect to emergency preparedness. What are the essential things that everybody does? What is it that is very different from jurisdiction to jurisdiction?

NACCHO also works very closely with CDC and state partners in very specific ways, getting down into the tactical. She very much thanked CDC for a change that NACCHO has noticed over the last year to 18 months in terms of really reaching out to get a variety of voices. An excellent example was the rapid task force at the end of June to July to capture some issues that occurred during the spring, and then to create jointly an action plan going forward for CDC in its preparation for the fall. That was, in her experience in 15 years or so in public health in the US, unique. She thought everybody there, CDC and partners, found that to be highly valuable.

Also on the tactical end, every local jurisdiction that she is aware of is all about planning for H1N1, but they still have to convene and coordinate a private health care system in the face of what could be difficult, even if the best case scenario occurs. The logistics and the messaging around two separate vaccine campaigns with entirely different target groups and entirely different schedules is going to be a challenge, which most of them have not seen before.

Ask-the-Board Session

Ellen MacKenzie, Ph.D., Member, COTPER BSC

Dan Sosin, M.D., M.P.H., Senior Advisor for Science, COTPER

Dr. Mackenzie noted that unfortunately, there was not going to be time to for the Ask-the-Board session. She requested that Dr. Sosin say a few words about this great idea. She suggested that consideration be given to having this session during the next meeting.

Dr. Sosin responded that this addressed a comment previously made by a BSC member regarding bringing them in to hear from them. The environment is constantly changing, and COTPER only sees the members a few times a year. It would be beneficial to have the flexibility to throw a new question out, ideally with some advanced time to think about it. He stressed that even though they ran out of meeting time, they should feel free to share their views and perspectives through other mechanisms such as emails. One lesson from this meeting was that they would plan to schedule this type of session earlier in the process, so that they would have a chance to engage in an open conversation and really energize the group around a few of the BSC's ideas.

Public Comment – Day 2

No public comments were offered during the second day of the meeting.

Closing Remarks / Adjourn

Ellen MacKenzie, Ph.D., Member, COTPER BSC

**Barbara Ellis, Ph.D., Deputy Associate Director for Science, COTPER
Designated Federal Official, COTPER BSC**

Dan Sosin, M.D., M.P.H., Senior Advisor for Science, COTPER

Dr. MacKenzie indicated that in the coming year, a workgroup would be established to evaluate the Career Epidemiologic Field Officer Program, for which Dr. Ellis would be distributing a notice defining the charge for that workgroup, and requesting volunteers.

Dr. Ellis thanked everyone for their time, stressing how incredibly valuable it was to COTPER and CDC to have their input and support. She reminded everyone that the BSC members and liaisons were invited to join them for a farewell celebration for Dr. Besser, and she bid everyone safe travels home.

Dr. Sosin offered his gratitude as well, acknowledging that there were a few bumpy times during the meeting, which was all part of a family reunion. Everyone is doing their best to understand each other's perspectives, to share as much as is helpful and useful, and to continue to evolve.

With no further business posed, the meeting was officially adjourned.

Certification

With no further business raised or discussion posed, Dr. Ellis officially adjourned the COTPER BSC meeting.

I hereby certify that to the best of my knowledge, the foregoing minutes of the August 13-14, 2009 COTPER BSC meeting are accurate and complete:

November 11, 2009

Date

/S/

Barbara Ellis, Ph.D.
Designated Federal Official, COTPER BSC

Appendix A: Membership Roster**Coordinating Office for Terrorism Preparedness and Emergency Response
Board of Scientific Counselors****Membership List****Chair**

Vacant

Executive Secretary

Barbara A. Ellis, Ph.D.

Deputy Associate Director for Science
COTPER - CDC
Atlanta, GA

Board Members**John (Jack) Harrald, Ph.D.**

Research Professor
Center for Technology, Security, and Public
Policy, Virginia Polytechnic and State
University
Alexandria, VA
Term: 2/12/2008 – 9/30/2009

Sharona Hoffman, J.D., L.L.M

Professor of Law and Bioethics
Case Western Reserve University School of
Law
Cleveland, OH
Term: 2/6/2008 – 9/30/2012

Ellen MacKenzie, Ph.D.

Professor and Chair
Department of Health Policy and
Management Johns Hopkins University
Bloomberg School of Public Health
Baltimore, MD
Term: 2/6/2008 – 9/30/2011

John (Jack) Muckstadt, Ph.D.

Professor
School of Operations Research and
Industrial Engineering - Cornell University
Ithaca, NY
Term: 2/5/2008 – 9/30/2010

Louis Rowitz, Ph.D.

Director
Mid-America Regional Public Health
Leadership Institute - University of Illinois at
Chicago, School of Public Health
Chicago, IL
Term: 2/18/2008 – 9/30/2012

William Stephens, M.S.

Advanced Practice Center Manager
Tarrant County Public Health
Fort Worth, TX
Term: 2/7/2008 – 9/30/2009

Robert J. Ursano, M.D.

Chairman, Department of Psychiatry
Uniformed Services University of Health
Sciences
Bethesda, MD
Term: 6/25/08 – 9/30/2012

Ex Officio Members**U.S. Department of Health and Human Services (HHS)****Mary Mazanec, M.D., J.D.**

Deputy Assistant Secretary for Preparedness and Response, and Director, Office of Medicine, Science, and Public Health

Office of the Assistant Secretary for Preparedness and Response (ASPR)

U. S. Department of Health and Human Services

Washington, DC

U.S. Department of Homeland Security (DHS)**Terry A. Adirim, M.D., M.P.H.**

Senior Medical Advisor - Office of Health Affairs

U.S. Department of Homeland Security

Washington, DC

U.S. Department of Defense (DoD)**Amy Kircher, M.P.H., Dr.PH.**

Epidemiologist, Office of the Command Surgeon

NORAD – US Northern Command

Petersen AFB, CO

**Coordinating Office for Terrorism Preparedness and Emergency Response
Board of Scientific Counselors**

Liaison Representatives

Association of Public Health Laboratories (APHL)

Mary J. Gilchrist, Ph.D., D(ABMM)

Consultant, Public Health
Solon, IA

Association of Schools of Public Health (ASPH)

James W. Curran, M.D., M.P.H.

Dean, Rollins School of Public Health
Co-Director, Emory Center for AIDS Research
Emory University
Atlanta, GA

Association of State and Territorial Health Officials (ASTHO)

Damon T. Arnold, M.D., M.P.H.

Director, Illinois Department of Public Health
Chicago, IL

Council of State and Territorial Epidemiologists (CSTE)

Patricia Quinlisk, M.D., M.P.H.

Medical Director and State Epidemiologist
Iowa Department of Public Health
Des Moines, IA

National Association of County and City Health Officials (NACCHO)

Karen Smith, M.D., M.P.H.

Public Health Officer and Director of Public Health
Napa County Health and Human Services Agency Public Health Division
Napa, CA

National Indian Health Board (NIHB)

Vacant

Appendix B: List of Attendees

Coordinating Office for Terrorism Preparedness and Emergency Response Board of Scientific Counselors

CDC Attendees

| <u>Last Name</u> | <u>First Name</u> | <u>Center/Office</u> |
|------------------|-------------------|----------------------|
| Anason | Andrea | COTPER |
| Aria | Sharefa | COTPER |
| Austin | Lynn | COTPER |
| Bakal | Joey | COTPER |
| Bashor | Mark | COTPER |
| Besser | Richard | COTPER |
| Biagioni | Mark | COTPER |
| Brown | Tara | COTPER |
| Brown | Tiffany | COTPER |
| Bryan | David | COTPER |
| Campolucci | Sharon | COTPER |
| Casey | Denise | COTPER |
| Cervantes | Miguel | COTPER |
| Chow | Cathy | COTPER |
| Cord | Meredith | COTPER |
| Diliddo | Colleen | COTPER |
| Ellis | Barbara | COTPER |
| Gadsden-Knowles | Kim | COTPER |
| Gorman | Sue | COTPER |
| Gould | Deborah | COTPER |
| Green | Mark | COTPER |
| Griffiths | Sean David | OD/OC SO |
| Harrell | Kerry | COTPER |
| Henkel | Richard | COTPER |
| Hurse | Jihan | COTPER |
| Jones | Terrance | COTPER |
| Kanter | Theresa | COTPER |
| King | Wanda | COTPER |
| King | Keesler | COTPER |
| Kokor | Valerie | COTPER |
| Kosmos | Christine | COTPER |
| Lebovitz | Robyn | COTPER |
| Leeman | Gregg | COTPER |
| Leifer | Corinne | COTPER |
| Leinhos | Mary | COTPER |
| Lindsey | Kim | COTPER |
| Logan | Marinda | COTPER |
| Lyday | Kevin | COTPER |
| Manheim | Diane | CCHP |
| Matthews | Clint | COTPER |
| McLees | Anita | COTPER |

| | | |
|------------------|-----------|----------|
| McMichael | Janice | COTPER |
| Meijer | Cecilia | COTPER |
| Mumford | Karen | COTPER |
| O'Connor | Ann | COTPER |
| O'Connor | Jean | COTPER |
| O'Meara | Gabrielle | COTPER |
| Popovic | Tanja | OD/OC SO |
| Porter | Kaitlin | COTPER |
| Ready | John | COTPER |
| Richmond | Alyson | COTPER |
| Rose | Dale | COTPER |
| Rouse | Ed | COTPER |
| Salter | Monique | COTPER |
| Schnepf | Laurie | COTPER |
| Shumock | Nick | COTPER |
| Singleton | Christa | COTPER |
| Slifkin | Gideon | COTPER |
| Smith | Gregory | COTPER |
| Sosin | Dan | COTPER |
| Stephens | Jimmy | OD/OC SO |
| Tabladillo | Mark | COTPER |
| Taylor | Angela | COTPER |
| Thomas | Craig | COTPER |
| Tierney | Linda | COTPER |
| Twedt | Tru | COTPER |
| Walton | Jessica | COTPER |
| Wan | Ellen | COTPER |
| Wasil | Julie | COTPER |
| Weaver | Vince C. | COTPER |
| Weir | Stefan | COTPER |
| Weyant | Robbin | COTPER |
| Williams-Johnson | Mildred | COTPER |
| Wooster | Mark | COTPER |
| Zaza | Stephanie | COTPER |

Public Attendees

| <u>Last Name</u> | <u>First Name</u> | <u>Affiliation</u> |
|------------------|-------------------|-----------------------------------------------------------------------------------|
| Austin | Thomas | Boeing |
| Biesiadecki | Laura | Association of Schools of Public Health Homeland Security Studies and Analysis |
| Diaz | Gerald | Institute |
| Helsing | Karen | Association of Schools of Public Health |
| Mathews | Henry | HMM Inc. |
| Ryan | Jeff | Northcom |
| Salerno | Reynolds | Sandia National Labs |